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Survey and health assessment of phthalates in toys and other products for children

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Survey and health assessment of phthalates in toys and other products for children

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Foreword

This project on phthalates in toys, childcare articles and other products for children is carried during the period March to December 2014.

The report describes the results of the project, including the survey of the market and the results of the survey. The report describes which other products for children that were selected for chemical analyses for content and migration of phthalates. The results of the chemical analyses are presented and a risk assessment of the phthalates, which migrate from the analysed products for children, is performed. Finally, analyses of content of phthalates in toys and childcare articles selected by the Danish Environmental Protection Agency have been performed. These analyses are a part of the market surveillance program of the Danish Chemical Inspection Service concerning compliance of applicable legislation within the area.

The project is carried out by FORCE Technology.

The participants of the project were:

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The project was followed by a reference group consisting of Shima Dobel and Maiken Guldborg Rasmussen from the Chemical Unit, the Danish Environmental Protection Agency, as well as Karin B. Sørensen and Morten Thjellesen from the Chemical Inspection Service, the Danish Environmental Protection Agency.

The project was financed by the Danish Environmental Protection Agency.

Conclusion and summary

Background
Phthalates are a group of substances which are primarily used as plasticisers in polyvinyl chloride (PVC). The phthalates are not chemically bound in PVC and therefore they can migrate from products. Some phthalates are classified as toxic to reproduction and some phthalates are considered to have endocrine disrupting properties. Some phthalates may be endocrine disrupting by an antiandrogen mechanism of action which means that the phthalates reduce the production or block the action of male sex hormones. Several phthalates have a harmonised classification as a result of their antiandrogen effects. Therefore, certain phthalates are limited in toys and/or childcare articles in the EU and in Denmark while other phthalates as well as the use of phthalates in other types of products for children are not regulated.

In this project, the content, release, and exposure to phthalates from several different types of products for children are investigated:

- Toys used by children under 14 years during play.
- Childcare articles which are intended to or can be expected to be put into the mouth by children at the age 0-3 years.
- 'Other products for children' which are neither toys nor childcare articles but which are addressed to children below 14 years.

Purpose
The purpose of the project is to provide an overview of children's exposure to phthalates with antiandrogen effects from toys, childcare articles and other products for children as well as to perform market surveillance on the requirements in legislation concerning phthalates in toys and childcare articles. Furthermore, the purpose of this project is to investigate whether other products for children contain and release phthalates in concentrations which may be problematic for children.

The execution of the project
In this project, the market for toys, childcare articles and other products for children has been surveyed. An investigation has been made whether phthalates are identified in these three types of products in former investigations, and if so which phthalates. Furthermore, applicable legislation regarding phthalates has been described for toys, childcare articles and 'other products for children'.

The survey has provided the basis for the purchase of products for chemical analysis for the content of phthalates. Based on the survey, the Danish Environmental Protection Agency selected 34 toy products and 7 childcare articles for market surveillance. In co-operation with the Danish Environmental Protection Agency, it was decided that the 35 'other products for children', which were purchased for chemical analysis for a content of phthalates, were to be distributed on the following product types:

- Bicycle handles, including handlebar tape
- Mobile covers for smartphones and tablets as well as bags for mobiles
- Wrist watches (watch straps)

After this a migration analysis was made (for the group of 'other products for children') for the products which contained phthalates. Finally, a risk assessment of the use of these 'other products for children' was made. An overview of the elements in the project is stated in Table 1 below.

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TABLE 1
OVERVIEW OF THE PHASES OF THE PROJECT AND WHICH PHASES THAT ARE COMPLETED FOR THE THREE GROUPS OF PRODUCTS: TOYS, CHILDCARE ARTICLES AND 'OTHER PRODUCTS FOR CHILDREN'

Analysis results – toys and childcare articles
As described in Table 1, nine pieces of toys and one childcare article contained phthalates in concentrations above 0.05 %. Whether this content of phthalates is in compliance with the applicable legislation depends on the identified phthalate as well as the target group of the toys. Nine out of 10 products with an identified content of phthalate in a concentration above 0.05 % failed to comply with the legislation on phthalates. A product can fail to comply with for instance both the Statutory Order on toys and the REACH Regulation. In these cases, the requirements of the most restrictive legislation must be met.

- 8 products do not comply with the Statutory Order on toys BEK no. 13 of 10/01/2011.
- 8 products do not comply with the REACH Regulation no. 1907 of 18/12/2006 – Entry 51.
- One single product does not comply with the REACH Regulation no. 1907 of 18/12/2006 – Entry 52.
- One single product does not comply with the Statutory Order on phthalates BEK no. 855 of 05/09/2009.

Enforcement of illegal products will only be carried out for the most restrictive requirements. The market surveillance showed that 9 products did not comply with applicable legislation.

DEHP is the primary reason for the non-compliances, followed by DIBP in two cases and DINP as well as DNOP in a single case. Up to 28 % of DEHP in a doll (head), up to 32 % of DIBP in a ball, up to 0.2 % of DNOP as well as up to 25 % of DINP in a ball were identified. However, the ball with 25 % of DINP does comply with the legislation on phthalates as the ball cannot come into the mouth (diameter > 5 cm) and DINP is not classified as reprotoxic.

The general picture from the analyses is that in many products, DOTP (DEHT or dioctyltereftalat) was used as plasticizer. This is not a phthalate in common sense but a terephthalate which is used as an alternative to phthalates.

Analysis results – 'other products for children'
Out of the 35 'other products for children' which were analysed for phthalates, 10 products contained one or more phthalates in concentrations above 1 %. These products were 2 bicycle handles (handlebar tape), 6 mobile covers and 2 wrist watches. DEHP (in 9 products – highest concentration was 15 % in a wrist watch) and DINP (in 4 products – highest concentration was 39 % in a handlebar tape) were primarily identified.

Migration to artificial sweat was carried out on these 10 'other products for children' with a content of phthalates above 1 %. Migration of phthalates from three of these products occurred: a mobile cover (M02) and two wrist watches (U06 and U10). The migration was carried out for 24 hours for the wrist watches (i.e. assumed used all 24 hours) and for 4 hours for mobile covers (assumed to be carried around the neck and hung under a blouse against a naked stomach). These exposure times were considered to be realistic worst-case scenarios. Migration of DEHP and DIBP occurred and therefore a health assessment of these two phthalates was carried out.

Assessment of risk of antiandrogen effects from phthalates in three products for children
For the three 'other products for children', a RCR (Risk Characterisation Ratio) value of maximum 0.0003 is calculated, which means that none of these products constitutes a risk of antiandrogen effects for 6-year-old children at use. The low risk is due to a low migration of phthalates from the products and a limited absorption through the skin.

Assessment of the total risk of antiandrogen effects from phthalates from several sources

It is relevant to assess the total risk of exposure to phthalates from several sources. Phthalates are found in the indoor climate, both in air and dust as well as food. Previously, the risk of this background exposure has been investigated in the Danish Environmental Protection Agency's consumer projects (no. 103 and 117). In the present report, these two projects form the basis of the background exposure to phthalates with antiandrogen effects. RCR values for median or maximum background exposure are added up for all phthalates with antiandrogen effects and then added up with the RCR values for two of the three analysed products for children (mobile cover as well as the wrist watch with the highest migration). The risk assessment shows that the risk of antiandrogen effects from phthalates for 6-year-old children is low as the RCR value is 0.93 if the median values for the background exposure is used. If instead the maximum exposure is used for risk calculation, a risk of antiandrogen effects from phthalates for 6-year-old children may occur as the RCR value exceeds 1 (RCR = 2.7). However, it must be emphasised that the used exposure data for food is of an earlier date and represents values from *before* a ban on use of these phthalates in food contact materials took effect. Therefore, the exposure from food may be expected to be lower today. Similarly, investigations of phthalates in the indoor climate show that great variations are found between the individual households.

To get a complete picture of the risk of exposure to phthalates with antiandrogen effects, the following ought to be included in a total risk assessment:

- Exposure to phthalates from products which earlier have been analysed for phthalate migration (plastic sandals, shower curtain, eraser etc.).
- Exposure to phthalates from other consumer products which are not yet tested for content and migration of phthalates.

The exposure calculation carried out in earlier projects shows that realistic worst-case exposure from other already investigated consumer products may result in a total RCR value exceeding 1. Added up with the results from this report, it means that exposure to phthalates with antiandrogen effects may present a health risk in a realistic worst-case situation even if values based on average exposure for both indoor climate and food are used. This is due to the use of single products with a high content of phthalates with antiandrogen effects, such as plastic sandals and erasers as well as the fact that the exposure to food can be overestimated compared to the real values today. However, more recent investigations are missing to confirm this.

Thus, the conclusion of this report is that exposure to a few phthalates in single products, examined as a part of this project, does not constitute a risk but that the total exposure to more phthalates with antiandrogen effects from several different sources in a realistic worst-case scenario may constitute a health risk for 6-year-old children. A large part of the risk is due to the use of a few products with high contents of phthalates as well as assumptions that phthalates are still present in food like it was some years ago – which probably is an overestimation in relation to the real situation today.

1. Introduction

1.1 Background

Phthalates are a group of substances which are primarily used as plasticisers in polyvinyl chloride (PVC). The phthalates are not chemically bound in PVC and therefore they can migrate.

Some phthalates are classified as toxic to reproduction and some phthalates are considered to have endocrine disrupting properties. Therefore, certain phthalates are limited in toys and/or childcare articles in the EU and in Denmark while other phthalates as well as the use of phthalates in other types of products for children are not regulated.

According to the Danish Environmental Protection Agency's database of chemical substances in consumer products, phthalates are found in a large number of consumer products, as for instance in products for children, including toys, childcare articles or other products which children (below 14 years) are expected to use. Soft PVC is used for instance for beach balls, water wings, desk pads, dinner mats, imitation leather, tents, changing pads, footwear, rainwear, prints on textiles, shower curtains, oilcloths, bathing pools etc. Therefore, phthalates can be found in this type of products (Danish EPA, 2014; Forbrugerkemi, 2012).

As regulation only applies to some phthalates in toys and childcare articles, the risk may be that other products which children can be expected to use (in this project mentioned as 'other products for children') may contain phthalates. Therefore, children can be exposed to phthalates in connection with the use of these products – either via direct exposure when they use the products or through release to the air and dust indoor.

Thus it will be interesting to identify whether a health problem exists with regard to the content of phthalates in these 'other products for children'. See section 1.3 below for a more specific definition of the product groups: toys, childcare articles and 'other products for children'.

1.2 Purpose

The purpose of this project is to provide an overview of children's exposure to phthalates with antiandrogen effects from toys, childcare articles and other products for children as well as to control whether the requirements in legislation concerning phthalates in toys and childcare articles. Furthermore, the purpose of this project is to investigate whether other products for children contain and release phthalates in concentrations which may be problematic for children.

Therefore, the project has the following purpose:

1. Toys: A control (by a chemical analysis) is made to check whether the requirements for content of phthalates are met in selected toys.
2. Childcare articles: A control (by a chemical analysis) is made to check whether the requirements for content of phthalates are met in selected childcare articles.
3. 'Other products for children': The content of phthalates is investigated in selected products (by a chemical analysis) and a risk assessment is made to check whether the identified concentrations may be problematic for children. In the risk assessment, the total exposure of several phthalates with antiandrogen effects from several exposure sources is taken into account.

1.3 Definitions

1.3.1 Definition of product groups

In this report, the terms toys, childcare articles and 'other products for children' are used. Below, a detailed definition follows to explain the meaning of these product groups.

Toys are defined as in the Danish Statutory Order on toys (BEK no 13 of 10/01/2011), i.e. *"products which solely or partly are constructed or intended to be used by children below 14 years during play"*. Examples of toys are Barbie dolls and balls.

Childcare articles are defined differently in Danish and European (EU) legislation respectively. This is described in details in chapter 2 "Legislation". Therefore, in this project, there are two definitions of childcare articles – a product group described as "childcare articles (DK)" and a product group described as "childcare articles (EU)". These product groups cover the Danish and the European definition of legislation respectively and are as follows:

Childcare articles (DK) are defined as: *"any product which is intended to or is normally expected to be put into the mouth by children at the age 0-3 years (0-36 months), including especially pacifiers, bibs, jewelries and bathing equipment etc. "*BEK No. 855 dated 05/09/2009.

Childcare articles (EU) are defined as: *"any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children"* (REACH Regulation No. 1907 dated 18/12/2006).

Other products for children are defined as *products, which are neither toys nor childcare articles but which are addressed to children below the age of 14 years*. In principle, 'other products for children' are any other products addressed to children, which are defined neither as toys nor as childcare articles. Many different products are included, for instance a pencil case, a school bag, a lamp etc. However, a common aspect is that they are addressed to children which can be due to drawings or figures on the product or that the price is not high so children below 14 years of age can afford to buy the products.

Products for children are generally used in this report as an overall name for the products which this project deals with, i.e. toys, childcare articles and 'other products for children'.

1.3.2 Definition of phthalates

The term "phthalates" is generally used as a definition of esters (diesters) of *ortho*-phthalic acid which is an aromatic dicarboxylic acid where the two carboxylic acids are in *ortho* position on the benzene ring, as stated in Image 1 (to the left). The general chemical structure of phthalates is stated in Image 1 (to the right) where the ester side chains R and R' most often consist of chain lengths of C_4 to C_{13}. The ester side chains R and R' can be linear, branched or a combination of this as well as cyclic. Generally, both ester side chains are structurally identical but they can also be different (Mikkelsen et al. 2014). Same definition of phthalates is used in the Danish statutory order concerning the restriction on use of phthalates in toys and childcare articles (see section 2.3 "Statutory Order on phthalates BEK No. 855 dated 05/09/2009 (DK)").

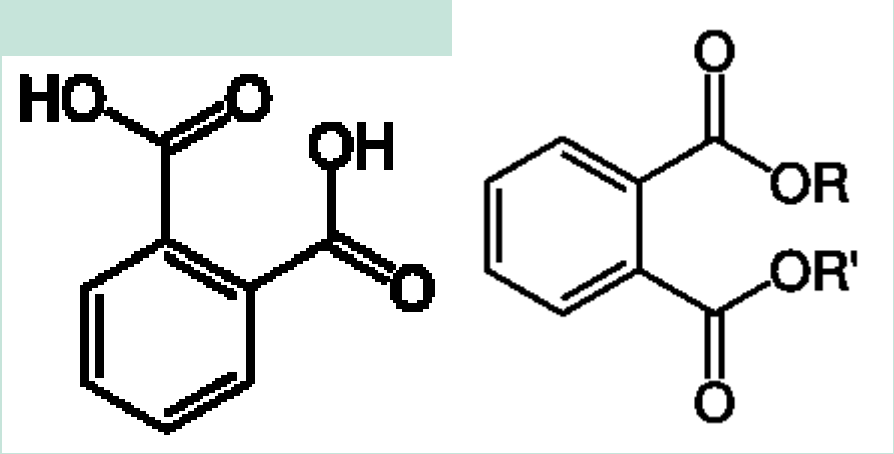


IMAGE 1
THE STRUCTURE OF O-PHTHALIC ACID (TO THE LEFT) AND ESTERS OF O-PHTHALIC ACID, I.D. PHTHALATES (TO THE RIGHT)

Phthalates are divided in high and low molecular phthalates (High/Low Molecular Weight Phthalate Esters (HMWPE/LMWPE)), (Danish Plastics Federation, 2014; American Chemistry Council, 2014). The low molecular phthalates can furthermore be divided into a low and medium group (US CPSC, 2010). Generally, the high molecular phthalates are regarded as being phthalates with 7-13 carbon atoms in the ester side chains (for instance DINP, DIDP, DNOP and DPHP) and the low molecular phthalates as being phthalates with 3-6 carbon atoms (including for instance DEHP, BBP, DIBP and DBP), (Danish Plastics Federation, 2014; American Chemistry Council, 2014).

Generally, the low molecular phthalates (especially with alkyl chains of 4-6 carbon atoms) are considered to be toxic to reproduction compared with the high molecular phthalates (Danish Plastics Federation, 2014; American Chemistry Council, 2014). As it is discussed later in this report, there are also high molecular phthalates which are suspected of having endocrine disrupting properties.

1.4 Use of phthalates

Phthalates are a group of plasticisers which are used to soften plastic – primarily PVC. Other types of plasticisers also exist but according to Danish Plastics Federation, phthalates constitute 87 % of the global market of plasticisers for PVC. The major part (96 %) of the plasticisers is used for production of soft PVC to so-called durable products as for instance electric cables, foils, floors or outdoor advertising. 4 % is used in more sensitive products as for instance medical equipment, food packaging and toys (Danish Plastics Federation, 2014). The use of high molecular phthalates amounts to almost 80 % of the quantity of phthalates used on the European market whereas the use of the low molecular phthalates amounts to under 11 % and has been decreasing during the last 10 years (Danish Plastics Federation, 2014). High molecular phthalates are used for instance in interior for cars, electrical insulation, vinyl floors, furniture, toys, garden hoses, back of carpets, footwear, rainwear and office supplies.

According to several sources (among others US CPSC, 2010; BCERC, 2007), primarily, the high molecular phthalates are used in toys but as many toys are produced outside the EU (primarily in the East) where the application pattern of phthalates is different than in the EU, it is still interesting to control the application of the low molecular phthalates, such as DEHP, DBP and BBP, which are restricted in the EU. According to RAPEX notifications, i.e. reports of products which constitute a serious risk, it is clearly shown that a lot of toys contain especially the low molecular phthalate

DEHP. Australian Competition & Consumer Commission states that the total amount of phthalate which is applied in a toy product will typically lie between 10 and 50 % dependent on how soft the material has to be (ACCC, 2014).

Besides the primary application as plasticiser in PVC, phthalates can be applied in elastomers[1] (as for instance rubber), coatings, adhesives and sealants. The phthalates can also be used in lubricants, thermoplastic polymers, rubber and selected paints and adhesives (US CPSC, 2010).

For materials which as a basis are soft such as rubber and elastomers, the amount of added phthalate will be smaller than for materials which as a basis are hard such as for instance PVC. The amount of applied phthalate in elastomers (rubber) will thus be significant smaller than in PVC. Furthermore, the amount of applied phthalate will depend on the type of phthalate that is used (Maag et al., 2010). As an example, amounts of phthalates of approx. 1-2 % are seen in elastomers such as bath mats and rubber coverings (safety mats) (Tønning et al., 2009 and Ottesen et al., 2011).

[1] An elastomer is a polymer with elastic properties, such as for instance rubber (acrylic rubber, butyl rubber, nitrile rubber, silicone rubber, natural rubber etc.) and thermoplastic elastomers such as EPDM (ethylene propylene dimer) and SEBS http://www.denstoredanske.dk/It%2c_teknik_og_naturvidenskab/Kemi/Kunststoffer%2c_polymerkemi%2c_plast_og_gummi/elastomerer

2. Legislation

Phthalates in products for children are regulated through the following legislation:

- REACH Regulation No. 1907 dated 18/12/2006 – Appendix XVII entry No. 51 and 52 (EU/DK).
- Directive on the safety of toys No. 48/2009 (EU) which is implemented in Danish legislation through BEK No. 13 dated 10/01/2011 concerning safety requirements of toys (DK).
- The Danish Statutory Order on phthalates BEK No. 855 dated 05/09/2009 on restriction of phthalates in toys and childcare articles (DK).

The regulations are summarised in Table 2 at the end of this chapter and are described in details in the individual sections below. The mentioned legislations operate with different definitions of the term childcare articles. This is described in details in the individual sections.

2.1 REACH Regulation No. 1907 dated 18/12/2006 (EU/DK)

According to Appendix XVII in REACH which deals with "restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles", in total six named phthalates are restricted:

- DEHP, DBP and BBP in toys and childcare articles.
- DINP, DIDP and DNOP in toys and childcare articles which can be placed in the mouth by children.
- For these six phthalates it applies that they are not allowed to be used as substances or in mixtures in concentrations above 0.1 % (by weight) of the softened material.

These limitations took effect in 2007 through EU Directive 2005/84 which was implemented in Danish legislation through "Statutory Order on restriction of phthalates in toys and childcare articles" (BEK No. 786 dated 11/7/2006) which today is historical and replaced by the REACH Regulation[2].

In a document from the EU Commission, it is specified that the limit value of 0.1 % applies for the total of DEHP, DBP and BBP as well as the total of DINP, DIDP and DNOP (European Commission, 2011a).

The phthalates are defined by the following CAS numbers:

- DEHP – CAS 117-81-7
- DBP – CAS 84-74-2
- BBP – CAS 85-68-7
- DINP – CAS 28553-12-0 ('pure' DINP) and CAS 68515-48-0 (mixed phthalate primarily with DINP)
- DIDP – CAS 26761-40-0 ('pure' DIDP) and CAS 68515-49-1 (mixed phthalate primarily with DIDP)
- DNOP – CAS 117-84-0

[2] http://www.retsinformation.dk/Forms/R0710.aspx?id=12943

Toys are defined like in the Statutory Order on toys (BEK No. 13 dated 10/01/2011), i.e. products which exclusively or partly are constructed or intended to be used by children under 14 years during play.

Childcare articles are defined as "any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children'. The term "childcare articles" does not contain any direct definition of age according to REACH. In English, the term "childcare articles" does not give any indication whether it is exclusively for small children as the Danish translation "articles for young children" does. In ECHA's "Guidance on requirements for substances in articles" (ECHA, 2011), reference to standards for childcare articles is made. The European Committee for Standardisation CEN's Technical Committee for childcare articles[3] operates with a term for childcare articles which is for "young children", i.e. small children. In a 'business plan[4]' for CEN/TC 252, it is defined that "childcare articles" are products which have the purpose to be used by children up to 4 years. Whether this definition is to be used in REACH context is, however, unclear. On the other hand, the limitation for the six phthalates applies for both toys and childcare articles and in the Statutory Order on toys, toys are defined for children from 0-14 years which may indicate that the term "childcare articles" is also applicable for 0-14 years. In practice, it must be realised that the age limit for childcare articles under REACH is not clearly defined. However, on their homepage, the Danish Environmental Protection Agency writes the following about phthalates: "In the EU, regulations for 6 specific phthalates in toys and childcare articles for children at the age of 0-14 years"[5] exist and thus the Danish EPA states that the regulations for childcare articles can also apply for older children if the articles can be included by the definition. Therefore, in this project, it is assumed that the age limit for childcare articles in REACH can theoretically include articles for children at the age of 0-14 years but practically, childcare articles will be for young children as a consequence of the definition.

As a starting point, it is assessed that a product or a constituent of a product (toy or childcare article) can be placed in the mouth if one of the dimensions is smaller than 5 cm which is described in a guiding document from ECHA[6].

All in all, it can be concluded that according to the REACH Regulation, the definition of childcare articles does not cover all kinds of products which are used for children – for instance, products like bicycle helmets, children's furniture or children's clothes are not included and therefore they belong to the category mentioned as 'other products for children' in this report.

Important aspects in relation to selection of products for analysis

In connection with selection of products for market surveillance regarding content of these six phthalates, it is thus interesting to:

- Select both toys and childcare articles as both product types are covered by the REACH Regulation.
- Select products which have a dimension that is smaller than 5 cm so it is possible for children to place the products in the mouth. These products are not allowed to contain any of the six phthalates regulated in REACH. Large products (where all dimensions are above 5 cm) are allowed to contain DINP, DIDP and DNOP. With regard to exposure, it is most interesting to focus on toys and childcare articles with at least one dimension below 5 cm which can be placed in the mouth by children.
- Select products for all age groups (0-14 years) as the regulations for toys and childcare articles are applicable for 0-14 years. However, with regard to exposure it is most interesting to focus

[3] http://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:6233&cs=1F8DFD4711BE021D1FCDBEDF93FDD465B
[4] http://standards.cen.eu/BP/6233.pdf
[5] http://mst.dk/virksomhed-myndighed/kemikalier/regulering-og-regler/faktaark-om-kemikaliereglerne/ftalater/
[6] https://echa.europa.eu/documents/10162/13645/guideline_interpretation_concept_mouth_en.pdf

on toys and childcare articles for young children (i.e. children at the age 0-3 years) who typically place the products in the mouth.

2.2 Statutory Order on toys BEK No. 13 dated 10/01/2011 (EU/DK)

The Danish statutory order on safety requirements for toy products – the Statutory Order on toys (BEK nr. 13 dated 10/01/2011) – implements the EU Toy directive (Directive No. 48, 2009). In Appendix II of the Statutory Order on toys (which describes "particular safety requirements"), section III "Chemical properties" states that:

- Substances which are classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Repr) (CMR substances) of category 1A, 1B or 2 under EU Regulation 1272/2008 (CLP Regulation, 2008) shall not be used in toys, in components of toys or in micro-structurally distinct parts of toy. "Micro-structurally distinct" toy parts are to be understood as the term "homogeneous materials[7] which is used in the RoHS Directive (European Commission, 2011b).

This regulation on CMR substances is relevant for phthalates as a number of phthalates are classified as reprotoxic, i.e. they are so-called CMR substances. Thus, this regulation will be applicable for the phthalates which have a harmonised classification as Repr. 1A, 1B or 2, and also for the phthalates which are not classified as Repr., but which meet the criteria for classification as reprotoxic.

However, a number of exceptions exist where CMR substances may be used:

- CMR substances are allowed to be used if they are contained in concentrations equal to or smaller than the relevant concentrations established in the CLP Regulation (2008) in connection with the classification of mixtures which contain these substances. I.e. CMR substances are allowed in concentrations below the classification limits for the individual substances. If no specific classification limit has been set for the individual substances, the general classification limits are applicable as follows:
  - Until 1 June 2015:
    - Repr. 1A and 1B (earlier called Repr.1 and 2) – 0.5 %
    - Repr. 2 (earlier called Repr. 3) – 5.0 %
  - From 1 June 2015 where the CLP Regulation takes full effect:
    - Repr. 1A and 1B – 0.3 %
    - Repr. 2 – 3.0 %
- Furthermore, CMR substances are allowed to be used
  - if they in any form are inaccessible for children, including inhalation when the toy is used,
  - or if they are listed in Appendix A, i.e. that the use of the substance or mixture has been evaluated by the relevant scientific committee and found safe, especially concerning the exposure. Appendix A contains for the time being (March 2014) only nickel which has the classification as Carc 2. Nickel is allowed for use in stainless steel in toys as it is assessed to be safe to use.
- Finally, CMR substances are allowed to be used if they meet the conditions stipulated in the legislation for materials in contact with foods (Regulation No. 1935, 2004) unless specific limit values are stipulated in Appendix C (none is set yet as per March 2014). For food contact materials among other things, a number of migration limit values are stipulated which have to be met for materials of plastic for certain substances.

[7] In the RoHS Staturory Order, a homogenic material is defined as "either a material of totally homogeneous composition or a material which consists of a combination of materials which cannot be separated or split into different materials mechanically, such as through screwing, cutting, breaking, painting or grinding processes" (www.retsinformation.dk/forms/R0710.aspx?id=143493)

Important aspects in relation to selection of products for analysis

In connection with selection of products for market surveillance regarding content of phthalates classified as a CMR substance, it is thus interesting to:

- Select toys but not childcare articles as the regulation concerning the content of CMR substances exclusively applies for toys.
- Select toys for all age groups (0-14 years) as the regulations for toys are applicable for the age group 0-14 years. However, with regard to exposure, it is most interesting to focus on toys for young children (i.e. 0-3 years old) who typically place the products in their mouth.

2.3 Statutory Order on phthalates BEK No. 855 dated 05/09/2009 (DK)

Since 1999, it has been restricted in Denmark to produce, import or place toys and certain childcare articles on the market with phthalates for children below the age of 3 years[8]. The restriction applies for all phthalates. In Statutory Order No. 855 dated 05/09/2009 on restriction of phthalates in toys and childcare articles, it is stated as follows:

- It is restricted to use phthalates as substances or as constituents in chemical products, when producing toys and childcare articles or parts of these in concentrations above 0.05 % (by weight).
- It is restricted to import or place toys and childcare articles or parts of these on the market which contain phthalates in concentrations above 0.05 % (by weight).

However, the following exceptions from the general restriction exist:

- The restriction does not apply for the phthalates which are mentioned in Appendix 1 of the statutory order, i.e. DEHP, DBP, BBP, DINP, DIDP and DNOP corresponding to the phthalates which are restricted through REACH Appendix XVII (as described above).
- Childcare articles which are intended to get into contact with foods are not covered by the restriction (other regulations apply for food contact materials).

In this statutory order, the definitions are as follows:

- In this statutory order, toys are only for children at the age of 0-3 years (0-36 months).
- Childcare articles are defined as ”any product which is intended to or normally is expected to be placed in the mouth by children at the age of 0-3 years (0-36 months), including especially pacifiers, bibs, jewelries and bathing equipment etc.”.
- Phthalates are defined as esters of o-phthalic acid.

It has to be noted that in the Danish Statutory Order on phthalates, a different term for childcare articles is used than the one used in the EU legislation (REACH Appendix XVII). In the Danish Statutory Order on phthalates, childcare articles are regarded as all types of products which are expected to be placed in the mouth by children at the age of 0-3 years whereas the EU definition of childcare articles deals with products which are intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. It is important to note when it is defined which legislation the selected products for market surveillance fall under.

All in all, it can be concluded that according the Danish Statutory Order, the definition of childcare articles does not cover all kinds of products which can be used by children – for instance, products like bicycle helmets or children’s furniture are not included and therefore they belong to the category mentioned as ‘other products for children’ in this report.

Important aspects in relation to selection of products for analysis

In connection with selection of products for market surveillance regarding the content of phthalates, it is thus interesting to:

[8] http://mst.dk/virksomhed-myndighed/kemikalier/regulering-og-regler/faktaark-om-kemikaliereglerne/ftalater/

- Select both toys and childcare articles for children under the age of 3 years as the regulations exclusively cover this age group and both product types are included in the Danish statutory order.

2.4 Complete overview of legislation regarding phthalates

Regulations applicable for phthalates in toys, childcare articles and 'other products for children' are summarised in Table 2.

Legislation	Applica-ble in	Applicable for			Limit value	Which phthalates?
		Toys	Childcare articles	'other products for children'		
REACH Regulation **Annex XVII**	DK/EU	**Toys** 0 – 14 years	**Childcare articles**: "Any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children" *The age limit is not defined*	Not applicable	0.1 % (total concentration of the three phthalates)	DEHP, DBP and BBP
		Toys, which can be placed in the mouth by children (i.e. diameter < 5 cm) 0 – 14 years	**Childcare articles**, which can be placed in the mouth by children (i.e. diameter < 5 cm) *The age limit is not defined*	Not applicable	0.1 % (total concentration of the three phthalates)	DINP, DIDP and DNOP
Statutory Order on toys	DK/EU	**Toys** 0 – 14 years	Not applicable	Not applicable	For Repr. 1A and 1B substances: 0.5 % For Repr. 2 substances: 5 %	Phthalates which are classified as reprotoxic
Statutory Order on phthalates	DK	**Toys** 0-3 years	**Childcare articles** "Any products which is intended to or normally can be expected to be placed in the mouth by children at the age 0-3 years"	Not applicable	0.05 %	All phthalates, except for DEHP, DBP, BBP, DNOP, DINP and DIDP

TABLE 2
OVERVIEW OF DANISH/EU LEGISLATION ON PHTHALATES. REGULATIONS MARKED WITH GREEN BACKGROUND COLOUR ARE NOT APPLICABLE.

3. Relevant phthalates

In this chapter, it is explained which phthalates that are relevant in relation to both analyses performed for market surveillance and the analyses of the 'other products for children'. These phthalates are overall the following:

- For the products for market surveillance it depends on which legislation that is applicable. This is further described in section 3.1:
  - The Danish Statutory Order on toys: Phthalates classified as reprotoxic
  - The REACH Regulation: The phthalates DEHP, DBP, BBP, DINP, DIDP and DNOP
  - The Danish Statutory Order on phthalates: All phthalates (except the six phthalates regulated under REACH)
- For the analyses of the 'other products for children' where no limitations on the content of phthalates exist, instead it depends on whether phthalates are present in the products in concentrations which are hazardous to health. Here focus is on phthalates with antiandrogen effects.

In this project, no assessments are made whether the described phthalates are reprotoxic and/or antiandrogen. I.e. phthalates which are classified as being reprotoxic but not stated as antiandrogen can probably act via an antiandrogen mechanism. It has not been the purpose of this project to determine this. The starting point has been ECHA's C&L Database which lists the harmonised classifications of substances as well as existing reports which have assessed which phthalates that have an antiandrogen mechanism of action, such as:

- The Danish Environmental Protection Agency's project "Exposure of pregnant consumers to suspected endocrine disruptors" (Andersen et al., 2012).
- Report from CeHoS (Centre on Endocrine Disrupters) "Evaluation of 22 SIN List 2.0 substances according to the Danish proposal on criteria for endocrine disrupters" (Hass et al., 2012).
- The Danish Environmental Protection Agency's strategy for phthalates (the Danish Environmental Protection Agency, 2013).

3.1 Relevant phthalates in connection with market surveillance

In this section, it is explained which phthalates to be analysed for in connection with the analyses of the products for market surveillance which have been selected by the Danish Environmental Protection Agency's Chemical Inspection Service.

The products for market surveillance are all covered by one or more of the below statutory orders/regulation:

1) The Danish Statutory Order on toys BEK No. 13 dated 10/01/2011 (EU/DK)
2) REACH Regulation No. 1907 dated 18/12/2006 (EU/DK) – Entry 51
3) REACH Regulation No. 1907 dated 18/12/2006 (EU/DK) – Entry 52: dimension < 5 cm (i.e. can be placed in the mouth)
4) The Danish Statutory Order on phthalates BEK No. 855 dated 05/09/2009 (DK)

The products for market surveillance can be divided into the below product groups. For each product group, it is stated in brackets which of the above legislations that the product group has to comply with:

A. Toys for children > 3 years which **cannot** be placed in the mouth (1) (2)
B. Toys for children > 3 years which can be placed in the mouth (1) (2) (3)
C. Toys for children < 3 years which **cannot** be placed in the mouth (1) (2) (4)
D. Toys for children < 3 years which can be placed in the mouth (1) (2) (3) (4)
E. Childcare articles > 3 years which **cannot** be placed in the mouth (2)
F. Childcare articles > 3 years which can be placed in the mouth (2) (3)
G. Childcare articles < 3 years which **cannot** be placed in the mouth (2) (4)
H. Childcare articles < 3 years which can be placed in the mouth (2) (3) (4)

The table below shows the number of products selected for market surveillance as well as which phthalates that are regulated in each product group.

The table below shows references to the following two ”not precisely defined” groups of phthalates:

- All phthalates (except for DEHP, DBP, BBP, DNOP, DINP and DIDP)
- Phthalates classified as reprotoxic (i.e. Repr. 1A, 1B and 2 substances)

In section 3.1.1 and 3.1.2, it is described which phthalates these two groups include.

Product group	Definition (in brackets, the applicable legislation is stated – see above).	Number of products selected for market surveillance	Regulated phthalates	Limit value
A	Toys for children > 3 years which **cannot** be placed in the mouth (1) (2)	4	(1): Phthalates classified as reprotoxic (i.e. Repr. 1A, 1B and 2). (2): DEHP, DBP and BBP	(1): Repr. 1A and 1B substances: 0.5 % Repr. 2 substances: 5 % (2): 0.1 % (total conc. for all three)
B	Toys for children > 3 years which can be placed in the mouth (1) (2) (3)	15	(1): Phthalates classified as reprotoxic (i.e. Repr. 1A, 1B and 2). (2): DEHP, DBP and BBP (3): DINP, DIDP, DNOP	(1): Repr. 1A and 1B substances: 0.5 % Repr. 2 substances: 5 % (2): 0.1 % (total conc. for all three) (3): 0.1 % (total conc. for all three)
C	Toys for children < 3 years which **cannot** be placed in the mouth (1) (2) (4)	3	(1): Phthalates classified as reprotoxic (i.e. Repr. 1A, 1B and 2). (2): DEHP, DBP and BBP (4): All phthalates (except for DEHP, DBP, BBP, DNOP, DINP and DIDP)	(1): Repr. 1A and 1B substances: 0.5 % Repr. 2 substances: 5 % (2): 0.1 % (total conc. for all three) (4): 0.05%
D	Toys for children < 3 years which can be placed in the mouth (1) (2) (3) (4)	12	(1): Phthalates classified as reprotoxic (i.e. Repr. 1A, 1B and 2). (2): DEHP, DBP and BBP (3): DINP, DIDP, DNOP (4): All phthalates (except for DEHP, DBP, BBP, DNOP, DINP and DIDP)	(1): Repr. 1A and 1B substances: 0.5% Repr. 2 substances: 5% (2): 0.1 % (total conc. for all three) (3): 0.1 % (total conc. for all three) (4): 0.05 %

Product group	Definition (in brackets, the applicable legislation is stated – see above).	Number of products selected for market surveillance	Regulated phthalates	Limit value
E	Childcare articles > 3 years which **cannot** be placed in the mouth (2)	-	(2): DEHP, DBP and BBP	(2): 0.1% (total conc. for all three)
F	Childcare articles > 3 years which can be placed in the mouth (2) (3)	-	(2): DEHP, DBP and BBP (3): DINP, DIDP, DNOP	(2): 0.1 % (total conc. for all three) (3): 0.1 % (total conc. for all three)
G	Childcare articles < 3 years which **cannot** be placed in the mouth (2) (4)	-	(2): DEHP, DBP and BBP (4): All phthalates (except for DEHP, DBP, BBP, DNOP, DINP and DIDP)	(2): 0.1 % (total conc. for all three) (4): 0.05 %
H	Childcare articles < 3 years which can be placed in the mouth (2) (3) (4)	7	(2): DEHP, DBP and BBP (3): DINP, DIDP, DNOP (4): All phthalates (except for DEHP, DBP, BBP, DNOP, DINP and DIDP)	(2): 0.1 % (total conc. for all three) (3): 0.1 % (total conc. for all three) (4): 0.05 %
	Products selected in total	41		

TABLE 3
NUMBER OF PRODUCTS FOR MARKET SURVEILLANCE IN THE RESPECTIVE PRODUCT GROUPS AS WELL AS DESCRIPTION OF WHICH PHTHALATES THAT ARE REGULATED IN EACH PRODUCT GROUP

3.1.1 All phthalates

It is only the Danish Statutory Order on phthalates which regulates "all phthalates". In the statutory order, it is specified that the expression "all phthalates" means "*phthalates as esters of o-phthalic acid*"; i.e. all phthalates which "fulfil" the chemical structure described in section 1.3.2. As earlier mentioned, the following phthalates are not covered by the Danish Statutory Order on phthalates: DEHP, DBP, BBP, DNOP, DINP and DIDP.

3.1.2 Phthalates classified as reprotoxic

In the table below, the phthalates which have a harmonised classification as reprotoxic (i.e. Repr. 1A, 1B and 2) are listed. Phthalates for which a proposal for a reprotoxic classification exists are also included. Phthalates which have a notified classification as reprotoxic (but not a harmonised classification) are not stated in the table. These phthalates are not included by the legislation (as being reprotoxic) – which for instance applies for DINP. Thus, DINP is an example of a phthalate which is not classified as reprotoxic but which is regarded as being antiandrogen (see Table 5). A complete list of phthalates and their harmonised classification, notified classification, notifications in articles, registrations as well as information on which phthalates that are on the Candidate list in REACH can be found in Appendix 1:.

Furthermore, the following information is stated in the table:

- The harmonised classification of the phthalates
- Whether the phthalates have antiandrogen effects
- Whether the phthalates are registered in the REACH system (as of April 2014)

It has to be noted that several phthalates can have the same abbreviation but different CAS numbers. For instance, DINP and DIHP are abbreviations of different phthalates with several CAS numbers. This is due to the fact that some phthalates are mixtures of several different phthalates, i.e. a mixture with varying chain lengths or side branches.

Phthalate	CAS No.	Harmonised classification	Registered	Comment
DCP/DCHP Dicyclohexyl phthalate	84-61-7	*Suggestion:* Repr. 1B, H360FD Skin Sens. 1 H317	Yes	Antiandrogen
DIBP Diisobutyl phthalate	84-69-5	Repr. 1B, H360Df	Yes	Antiandrogen
DBP/DnBP Dibutyl phthalate	84-74-2	Repr. 1B, H360Df Aquatic Acute 1, H400	Yes	Antiandrogen
BBP Benzyl butyl phthalate	85-68-7	Repr.1B, H360Df Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Yes	Antiandrogen

Phthalate	CAS No.	Harmonised classification	Registered	Comment
DEHP Bis(2-ethylhexyl) phthalate, di-(2-ethylhexyl) phthalate	117-81-7	Repr. 1B, H360FD	Yes	Antiandrogen
DMEP Bis(2-methoxyethyl) phthalate	117-82-8	Repr. 1B, H360Df	No	
DnPP Di-n-pentyl phthalate	131-18-0	Repr. 1B, H360FD Aquatic Acute 1, H400	No	Antiandrogen
DIPP Diisopentyl phthalate	605-50-5	Repr. 1B, H360FD Aquatic Acute 1, H400	Yes	
DHNUP 1,2-Benzendicarboxyl acid, di-C7-11-branched and linear alkyl esters	68515-42-4	Repr. 1B, H360Df	No	
DIHP 1,2-benzendicarboxyl acid, dihexyl ester, branched and linear Diisohexyl phthalate	68515-50-4	*Suggestion:* Repr.[9]	No	
DIHP 1,2-benzendicarboxyl acid, di-C6-8-branched alkyl esters, rich in C7	71888-89-6	Repr. 1B, H360D	No	
DPP 1,2-Benzendicarboxyl acid, dipentyl ester, branched and linear and linear/bis-C5-alkyl-(linear and branched) phthalate	84777-06-0	Repr. 1B, H360FD Aquatic Acute 1, H400	No	

[9] Der er forslag om en harmoniseret klassificering som reproduktionsskadende. Den præcise klassificering står ikke angivet. http://echa.europa.eu/registry-of-submitted-harmonised-classification-and-labelling-intentions/-/substance/57/search/68515-50-4/term

Phthalate	CAS No.	Harmonised classification	Registered	Comment
PIPP n-pentyl-isopentyl phthalate	776297-69-9	Repr. 1B, H360FD Aquatic Acute 1, H400	No	
DnHP Di-n-hexyl phthalate	84-75-3	Repr. 1B H360FD	No	Antiandrogen

TABLE 4
LIST OF PHTHALATES CLASSIFIED AS REPROTOXIC

3.2 Relevant phthalates in connection with analyses of 'other products for children'

In this section, it is explained which phthalates it is relevant to analyse for in connection with the analysis of 'other products for children'.

For 'other products for children' there are no limitations on which phthalates that are allowed in the products, cf. Table 2. Therefore, the only legislation which these products can fail to comply with– when it comes to phthalates – is thus the Product Safety Act which broadly prohibits producers to place a product on the market which can constitute a health risk for the consumer at use. I.e. available 'other products for children' which contain phthalates in such high concentrations that at a risk assessment they turn out to constitute a risk for children during use, the content of the phthalates are not in compliance with the provisions of the Product Safety Act (LAW No. 1262, 16/12/2009).

Phthalates which are in focus for 'other products for children' are the phthalates which have antiandrogen effects. These phthalates are listed in the table in the following section.

3.2.1 Phthalates with antiandrogen effects

Several phthalates are suspected of being endocrine disrupting and several phthalates have a harmonised classification as a result of their antiandrogen effects which means that they reduce the production or block the effect of male sex hormones. In a previous project from the Danish Environmental Protection Agency on endocrine disrupting substances which pregnant women may be exposed to, the following phthalates were assessed to have antiandrogen effects: DEHP, DINP, DBP, DIBP, BBP, DPP, DNHP, DNOP (Andersen et al., 2012).

On basis of the registration information on ECHA's homepage, for a number of phthalates registered under REACH, it is not possible immediately to assess whether they have antiandrogen effects or refuse that they have possible endocrine disrupting effects. However, they are used in large amounts and therefore it is relevant to investigate whether they can be found in products for children. In the table below, the phthalates listed are exclusively the phthalates which for certain can be considered to have antiandrogen effects (based on Andersen et al., 2012; Hass et al., 2012; the Danish Environmental Protection Agency, 2013). Many of these phthalates are registered and it can be expected that they are used in the EU. The two phthalates DPP and DNHP are not registered but are preregistered.

Phthalate	Name	CAS No.	Antiandrogene effects
DEHP	Di-(2-ethylhexyl) phthalate	117-81-7	Yes
DINP2	Diisononyl phthalate	28553-12-0	Yes
DBP	Dibutyl phthalate	84-74-2	Yes
DIBP	Diisobutyl phthalate	84-69-5	Yes
BBP	Benzyl butyl phthalate	85-68-7	Yes
DnPP	Di-n-pentyl phthalate	131-18-0	Yes
DnHP	Di-n-hexyl phthalate	84-75-3	Yes
DCHP (DCP)	Dicyclohexyl phthalate	84-61-7	Yes

TABLE 5
OVERVIEW OF PHTHALATES WITH ANTIANDROGEN EFFECTS

As phthalates with antiandrogen effects can cause serious health effects on children it is assessed that all phthalates with antiandrogen effects are to be evaluated if they are found in the analysed 'other products for children'.

4. Survey of phthalates in products for children

The previous chapter listed the phthalates that are regulated within the different product categories. However, this does not indicate which phthalates that are used in practice. Therefore, this chapter aims to give an overview of which phthalates that have been observed within the different product categories (children above/below 3 years, childcare articles, etc.) in the recent years.

The purpose of this chapter is to obtain input on which toys and childcare articles that should be in focus when selecting products for analyses. This also indicates which products that should be purchased and analysed under the product category 'other products for children'.

The survey of phthalates in products for children is carried out by review of the following:

- RAPEX (the rapid alert system for non-food dangerous products[10]).
- Reports that have described examples on identification of phthalates in toys.
- The survey database by the Danish EPA that shows in which survey projects[11] phthalates have been identified in consumer products.
- Various consumer tests from e.g. the Danish Consumer Council TÆNK, the Danish Information Centre for Environment and Health and the German test magazine Öko-Test.
- General internet search.

In the survey, multiple examples of phthalates found in toys, childcare articles and 'other products for children' have been identified. These examples are presented in three tables in Appendix 2: "Examples of phthalates identified in toys, childcare articles and 'other products for children'". All the examples listed concern products where a content of phthalates has been identified through chemical analysis. The examples have been categorised as either toys, childcare articles or 'other products for children'. If the source has stated which phthalates that have been identified and in which concentration, this has been indicated in the tables. In the case of multiple concentrations of the same phthalate in multiple products, the highest identified concentration has been stated.

In the following three chapters, the most essential information from Appendix 2: is presented. The information is also summarised in Table 6 at the end of this chapter. The most essential information includes:

- Identified phthalates
- Identified product types (where the phthalates have been identified)

4.1 Identified phthalates

As illustrated by Table 6, the phthalate DEHP is the substance that is observed most frequently in toys, childcare articles and 'other products for children'. Especially in the category toys, a predominance of registrations in the RAPEX that concerns findings of DEHP exists. These registrations are above the allowed limit value for the content of DEHP in toys in the EU. In 2013

[10] http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.search
[11] http://mst.dk/virksomhed-myndighed/kemikalier/fokus-paa-saerlige-produkter/database-over-kemiske-stoffer-i-forbrugerprodukter/

alone, 174 registrations on phthalates found in toys were reported. Most of them were due to exceeding values for DEHP. Besides DEHP; DINP, DBP, DIBP, DIDP (i.e. the phthalates limited in the EU) have been identified most frequently in toys, childcare articles and 'other products for children'.

In some specific cases, other phthalates besides the 6 phthalates, that are restricted in toys and childcare articles within the EU, have been identified. These other phthalates are:

- DPHP (CAS 53306-54-0) – is registered, not classified/notified as Repr.
- DCHP (CAS 84-61-7) – is registered, but does not have a harmonised classification as Repr. (however, a suggestion on a harmonised classification as Repr. 1B exists), is antiandrogen.
- DEP (CAS 84-66-2) – is registered, and notified as Repr.
- DUP (CAS 3648-20-2) – is registered, not classified/notified as Repr.
- BIP (CAS 17851-53-5) – is preregistered, but not yet registered. The phthalate does not appear in ECHAs C&L Database.
- BOP (CAS 84-78-6) – is preregistered, but not yet registered. The phthalate does not appear in ECHAs C&L Database.

It is worth noticing that the phthalates DPHP (seen in four examples) and DCHP (seen in a single product) (both high-molecular phthalates) only have been identified in consumer products described in references from 2013. This could indicate that these are new phthalates that are used as substitutes for e.g. DEHP. DCHP is antiandrogen, but at the time being no evaluations of DPHP being antiandrogen exist. According to information from ECHAs database of registered substances, DPHP is registered in the tonnage band 10,000 – 100,000 tons/year. This indicates that this phthalate is frequently used, where DCHP is registered in the tonnage band 100 – 1,000 tons/year. All in all, this could indicate that a trend of producers using high-molecular phthalates more frequently exists.

4.1.1 Materials identified in the survey

In general, there is little information regarding in which specific materials phthalates have been identified. This is the case for both RAPEX registrations and in various analysis reports. In most cases, it is only stated that the phthalates have been indentified in soft plastic (see Table 6). The phthalates are, however, also indentified in various products such as handles on bicycles and wheels on toy cars. Multiple examples of phthalates found in artificial leather and in plastic print on textiles have also been identified. Finally, a few other examples of phthalates found in for example lacquer, laminated cardboard and in some kind of artificial fabric have been listed. This artificial fabric has not been specified further in the example; hence, it is hard to determine exactly which material it is.

4.1.2 Products identified in the survey

Table 6 shows that phthalates have been identified in various different toys, childcare articles and 'other products for children'. In RAPEX, most cases reported for not being in compliance with the EU REACH legislation are mainly dolls with a content of phthalates (especially DEHP). This can, however, be an indication of the fact that more than one member state has carried out analysis of dolls. Besides this, there is no pattern in the product types that contain phthalates. Therefore, phthalates can potentially be present in various products targeted children. Common for the registrations in RAPEX is, however, that the majority of the products comes from the East (for example China or Hong Kong).

In Table 6 below, the most relevant information is presented. The full review is presented in Appendix 2: where it is stated in which part of the product the phthalates have been identified (if this is stated), for example if the phthalates have been identified in the head or arm of a doll. It is, however, far from all references that have presented this type of information.

	Toys	Childcare articles	'Other products for children'
Examples of products containing phthalates	Dolls, teddy bears Electronic dolls and teddy bears Play stroller Plastic animals, toy figures Wallet, wrist watch Rocking horse Balls Radio controlled car Piano Toy pistols with soft tip arrows Children masks, cowboy vests Children's books Beach toys Toy bags Markers, pencils, crayons, erasers, glitter pens, pencil cases Running bicycles (handle, saddle) Slimy toys	Push chairs Pacifiers Nursing pillows Baby mattresses Bedside for crib Toilet seats for children Bibs Baby sling Children's tub Children's seat for chair Children's chairs, high chairs for children Baby crawling carpet Strollers, prams, apron for strollers, prams and combo strollers	Artificial leather jacket Labels and reflexes on jackets, mittens etc. Children's wear, T-shirts (plastic print) Rainwear Plastic sandals, plastic shoes, Crocs Rubber boots Swim equipment, water wings Bathing pool Oilcloth, placemats Shower curtains Children's lamps Soap packaging Slip mats, figures for the tub School bags Beanbags Headphones Gaming consoles Car seats
Phthalates observed (number of examples is given in brackets)	DEHP (>> 23 – by far the most frequently observed in the examples, especially in RAPEX) DBP (9), DINP (9), DIDP (4), BBP (2), DIDP (2), DPHP (1)	DEHP (21), DINP (12), DIBP (3), DBP (3), DIDP (3), DEP (1), DPHP (1), DCHP (1), DUP (1)	DEHP (23), DINP (10), DBP (7), DIBP (6), DIDP (3), BBP (2), DEP (2), DPHP (2), DNOP (1), BIP (1), BOP (1)

TABLE 6
OVERWIEW OF EXAMPELS OF IDENTIFIED PHTHALATES WITHIN THE THREE PRODUCT GROUPS (TOYS, CHILDCARE ARTICLES AND 'OTHER PRODUCTS FOR CHILDREN')

5. Products for analysis

The following chapter describes how the selection of products has been carried out (taken into consideration the information given in the previous two chapters) – and lists the selected/purchased products.

5.1 Products selected for analysis

The overview of phthalates previous observed in products for children indicates that there is no special product group that should be focused on (besides the fact that dolls are often listed as a product containing phthalates). Therefore, products selected for analysis are selected on the basis of the following criteria:

- Focus on products made from soft plastic
- Examples of toys – for children both older and younger than 3 years (as far as possible)
- Examples of childcare articles – for children both older and younger than 3 years (as far as possible)
- Examples of toys/childcare articles that can be placed in the mouth by children
- Examples of dolls (with soft heads)
- Toys that have to be labelled with the CE mark
- Primary focus on relatively cheap products
- Products from different stores, including 'cheap stores'.

The Danish EPA's Chemical Inspection Service handled the selection of products for the analyses. The products have been selected during the period from May – July 2014. The products have been selected from among others the following types of stores:

- Toy stores
- Supermarkets
- DIY centres
- Sports shops
- Various discount stores with mainly cheap products

The table below lists the products that have been selected for analyses. In total 41 products were selected where 15 were analysed at two different spots on the product, thus the total number of analyses was 56.

No.	KI test no.	Product description	Type	Age estimated	Product-type (A - H from chapter 3.1)
1	495	Racket with ball	Toy	> 3 year	B
2	496	Ball	Toy	> 3 year	A

No.	KI test no.	Product description	Type	Age estimated	Product-type (A - H from chapter 3.1)
3	499	Beach toy	Toy	< 3 year	C
4	501	Space hopper	Toy	> 3 year	A
5	503	Plastic bucket	Toy	< 3 year	D
6	504	Space hopper with string	Toy	> 3 year	B
7	505	Doll	Toy	< 3 year	D
8	506	Ball	Toy	< 3 year	C
9	507	Doll with horse	Toy	> 3 year	B
10	508	Swim ring	Toy	> 3 year	B
11	510	Beach toy	Toy	> 3 year	B
12	511	Space hopper with string	Toy	> 3 year	B
13	512	Jump rope	Toy	> 3 year	B
14	516	Doll	Toy	> 3 year	B
15	517	Badminton set	Toy	> 3 year	A
16	520	Doll	Toy	< 3 year	D
17	521	Ball	Toy	< 3 year	C
18	522	Water wings	Childcare articles	PPE*	H
19	523	Water wings	Childcare articles	PPE*	H
20	524	Bathing west	Childcare articles	PPE*	H
21	525	Bathing pool	Toy	< 3 year	D
22	526	Beach toy	Toy	> 3 year	B
23	529	Bib	Childcare articles	< 3 year	H
24	530	Nursing pillow	Childcare articles	< 3 year	H
25	573	Swim ring	Toy	< 3 year	D
26	574	Swim ring	Toy	< 3 year	D
27	575	Swim ring	Childcare articles	< 3 year	H

No.	KI test no.	Product description	Type	Age estimated	Product-type (A - H from chapter 3.1)
28	576	Beach ball	Toy	< 3 year	D
29	577	Beach toy	Toy	< 3 year	D
30	578	Snorkel	Toy	> 3 year	B
31	580	Flippers	Toy	> 3 year	B
32	581	Snorkel	Toy	> 3 year	B
33	582	Water wings	Childcare articles	PPE*	H
34	588	Bathing pool	Toy	< 3 year	D
35	589	Doll	Toy	> 3 year	B
36	590	Doll	Toy	> 3 year	B
37	591	Bow with arrows	Toy	> 3 year	B
38	592	Doll	Toy	> 3 year	B
39	593	Rubber duck	Toy	< 3 year	D
40	617	Swim ring	Toy	< 3 year	D
41	618	Beach toy	Toy	< 3 year	D

*PPE – PERSONAL PROTECTION EQUIPMENT

TABLE 7
OVERVIEW OF SELECTED PRODUCTS FOR CONTROL

5.2 'Other products for children' selected for chemical analyses

The overview of phthalates in children's products observed up until now revealed that there is no special group of products within the category 'other products for children', that should be focused on. Phthalates have been observed in multiple different product types.

Therefore, it was decided in consultation with the Danish EPA that the product group 'other products for children' was to cover the 3 product types below. These product types were evaluated to be relevant because they can be made from soft PVC and thereby contain phthalates. These products could also contain other materials that could contain phthalates. In addition, children can have daily contact with these types of products.

- Bicycle handles as well as handlebar tape (called C01 to C11)
- Mobile covers (both for smart phones and tablets) and bags for mobiles (called M01 to M11)
- Wrist watches (i.e. watchbands) (called U01 to U12)

The products were purchased with consideration for the following criteria:

- Largely, the same amount of each product type was purchased
- The product consisted (insofar as it was possible to evaluate on-site when purchasing) of PVC i.e. as a minimum of soft plastic
- The products were produced in the East
- The products were relatively cheap (in order to appeal to children)
- The products appeal visually to children (i.e. have figures/pictures attached that appeal to children)
- The products are purchased in different stores, including some small stores

The products were purchased in the period May – June 2014.

Table 8 below shows the products that were purchased for chemical analysis. In total 35 products were purchased. One analysis per product was carried out.

No.	Product description	Type	Comment
C01	Black grip	Bicycle handle	
C02	Orange grip	Bicycle handle	
C03	Read grip	Bicycle handle	
C04	Outer surface, clear	Bicycle handle	
C05	Read grip	Bicycle handle	
C06	Green grip	Bicycle handle	
C07	Green grip	Bicycle handle	
C08	Pink grip	Bicycle handle	
C09	Blue	Bicycle handle	
C10	Blue ribbon without adhesive	Handlebar tape	
C11	Black ribbon without adhesive	Handlebar tape	
M01	Waterproof bag with string to hang around the neck. Transparent red and clear plastic	Mobile cover	For smart phones
M02	Red pocket made of artificial leather	Mobile cover	For smart phones
M03	Orange mobile cover for bags and sides – shaped as a cassette tape	Mobile cover	For smart phones
M04	Pink/clear bag from soft plastic. Waterproof. To hang around the neck	Mobile cover	For smart phones

No.	Product description	Type	Comment
M05	Clear and black waterproof cover of plastic	Mobile cover	For tablets
M06	Black cover for the back and sides. Possible to sew own pattern on the back	Mobile cover	For iPad
M07	Green and white mobile bag with strap	Mobile bag	For smart phones
M08	Black mobile bag made from artificial leather	Mobile bag	For tablets
M09	Clear and unclear waterproof cover	Mobile cover	For smart phones
M10	Clear and blue waterproof cover	Mobile cover	For smart phones
M11	Clear and pink cover from artificial leather	Mobile cover	For smart phones
M12	Blue cover for the back and sides	Mobile cover	For smart phones
U01	Orange children's wrist watch	Wrist watch	
U02	Purple children's wrist watch	Wrist watch	
U03	Pink wrist watch with hearts	Wrist watch	
U04	Smurfs wrist watch	Wrist watch	
U05	Yellow wrist watch with rhinestones	Wrist watch	
U06	Purple children's wrist watch	Wrist watch	
U07	Blue children's wrist watch with eyes	Wrist watch	
U08	Hello Kitty wrist watch	Wrist watch	
U09	Superman children's wrist watch blue	Wrist watch	
U10	Lightning McQueen children's wrist watch	Wrist watch	
U11	Wrist watch with Spiderman	Wrist watch	
U12	Wrist watch with Barbie	Wrist watch	

TABLE 8
OVERVIEW OF PURCHASED PRODUCTS IN THE CATEGORY 'OTHER PRODUCTS FOR CHILDREN'

6. Analysis method and results

In this chapter the following is described:

- Analysis method
- Detection limits
- Uncertainties
- Results of the analysis

The above mentioned elements are described separately for the analyses carried out on 'selected products for market surveillance' and the analyses of 'other products for children' respectively.

6.1 Analyses of products for market surveillance (toys and childcare articles)

6.1.1 Analysis method

The 41 control products were initially screened by use of the Beilstein test for the content of chlorine as an indicator for PVC. Afterwards, the PVC-products were screened by use of FTIR to identify products with a high content of phthalates, i.e. where the phthalates are typically used as a plasticiser.

The PVC tests were then dissolved in tetrahydrofuran (THF) followed by precipitation of appropriate dissolved polymer material by adding cyclohexane and products with a high level were further dissolved. Finally, a quantitative analysis of the phthalates was carried out by using GC/MS with internal standard (deuterated DEHP). The method is based on CPSC-CH-C1001-09.3 (2010).

The tests which are not PVC was cryogrinded to fine powder and extracted with THF in ultrasound and left standing overnight. Possibly dissolved polymer was precipitated with cyclohexane. The test was filtered and analysed by GCMS with internal standard (deuterated DEHP) as above.

The GCMS method was from the beginning calibrated against DIP, DBP, BBP, DEHP, DNOP, DINP and DIDP. Except from DIDP and DINP which have many single components with overlapping retention times, there is full separation of the phthalates. Other phthalates (besides the above mentioned) can be detected by spikes in the chromatograms with ion 149 m/z, which occurs with different retention times compared to the seven phthalates referred to above.

The chromatogram is approximated a boiling separation. This means that phthalates with higher molecular weight (DIDP and DINP at 17-20 min) are observed later compared to the lighter phthalates (DIBP and DBP i.e. at 9.8 and 10.6 min). Thus the retention time is a good indicator for which phthalate that is present. Phthalates at levels of detection can thereby be identified by the retention time. Furthermore, phthalates in higher amounts can be identified by the mass spectra.

6.1.2 Detection limits

The quantitative detection limit for the relevant phthalates depends on the individual phthalates and the appropriate matrix (plastic with possible additives). The typical detection limits are specified in Table 9 below.

Phthalate	Detection limit (weight % in plastic)
DIBP	0.02
DBP	0.01
BBP	0.02
DEHP	0.01
DNOP	0.01
DINP	0.03
DIDP	0.035

TABLE 9
OVERVIEW OF TYPICAL QUANTITATIVE DETECTION LIMITS

The real detection limit depends on the weighed amount of dilution of the sample. The real detection limit will be equal to or lower than the typical (the one given in the table above). In Table 11 (the results from the quantitative analyses), it will be possible to see values lower than the above listed, typical detection limits.

Other phthalates, besides the above mentioned, can be detected with approximately the same sensitivity. As illustrated by Appendix 3: the main part of the actually used phthalates is among these seven phthalates.

6.1.3 Uncertainties

As basically all phthalates have to be analysed (c.f. regulatory requirement of the Danish Statutory Order on phthalates (4)) – it is a complex manner to determine the uncertainties of the analysis of nearly all the phthalates beforehand. Below the uncertainties are indicated for the quantitative determination of *the identified* phthalates.

Phthalate	Uncertainty, % relative measurement value
DIBP	30
DBP	20
BBP	25
DEHP	20
DNOP	20

Phthalate	Uncertainty, % relative measurement value
DINP	30
DIDP	40

TABLE 10
OVERVIEW OF THE UNCERTAINTIES FOR THE IDENTIFIED PHTHALATES

It turned out that a relatively large number of products selected for market surveillance were plasticised with DOTP (DEHT) – dioctylterephthalate (CAS no. 6422-86-2). Even though a product is plasticised with DOTP (which is not covered by any legislation mentioned in this project), it is possible that the samples can contain small amount of other phthalates. It is possible to detect other known phthalates in the samples even though they contain DOTP, but other unknown spikes identified by GCMS are assumed to be other terephthalates. Furthermore, they are identified in so small quantities that it is not possible to make a credible spectrum and thereby credible quantification.

In general, the uncertainty of the reproducibility is about 20-30 % (40 % for DIDP), which means that a content of i.e. 0.1% in reality can be up to 30% less corresponding to a content of at least 0.13%, which does not comply with the legislation with a limit of 0.1%. It should be mentioned that it is normal with this level of uncertainty when determining phthalates.

6.1.4 Analytical results of analyses

In the following section, the analytical results for the samples for market surveillance are given. Initially the respective product groups as well as the relevant notices and regulation have been repeated.

1) The Danish Statutory Order on toys BEK No. 13 dated 10/01/2011 (EU/DK)
2) REACH Regulation No. 1907 dated 18/12/2006 (EU/DK) – Entry 51
3) REACH Regulation No. 1907 dated 18/12/2006 (EU/DK) – Entry 52: dimension < 5 cm (i.e. can be placed in the mouth)
4) The Danish Statutory Order on phthalates BEK No. 855 dated 05/09/2009 (DK)

The products for market surveillance can be divided into the below product groups. For each product group, it is stated in brackets which of the above legislations that the product group has to comply with:

A. Toys for children > 3 years which **cannot** be placed in the mouth (1) (2)
B. Toys for children > 3 years which can be placed in the mouth (1) (2) (3)
C. Toys for children < 3 years which **cannot** be placed in the mouth (1) (2) (4)
D. Toys for children < 3 years which can be placed in the mouth (1) (2) (3) (4)
E. Childcare articles > 3 years which **cannot** be placed in the mouth (2)
F. Childcare articles > 3 years which can be placed in the mouth (2) (3)
G. Childcare articles < 3 years which **cannot** be placed in the mouth (2) (4)
H. Childcare articles < 3 years which can be placed in the mouth (2) (3) (4)

Products that fail to comply with one or more of the above mentioned legislations are marked with bold in Table 11 below:

Sample no.	Product	Part analysed	Type	Product group	Quantified content of phthalate (weight %)	The product does not comply with the following legislation	Maximum permitted content
495	**Racket with ball**	**Ball**	**Toy**	**B**	**DEHP (26%)**	**DK Stat. Ord. on toys**	**0.5%**
						REACH – Entry 51	**0.1%**
496	Ball	Ball	Toy	A	DINP (25%)[12]	No violation	-
499	Beach toy	Beach toy	Toy	C	-		
501	Space hopper	Ball	Toy	A	DIBP (0.01 %) NB. May be as low as 0.007 % due to uncertainty	No violation	0.5%
503	Plastic bucket	Handle	Toy	D	-		
504	Space hopper with string	String	Toy	B	-		
505	Doll	Head	Toy	D	-		
506	**Ball**	**Ball**	**Toy**	**C**	**DIBP (32 %)[13]**	**DK Stat. Ord. on toys**	**0.5%**
						Statutory Order on phthalates	**0.05%**

[12] DINP is not classified and thereby not restricted by the Danish Statutory Order on toys. As in the case of a ball with a diameter above 5 cm, Entry 52 in REACH Annex XXVII is not applicable. In this case it is a toy for children above 3 years which means that it is not restricted by the Danish Statutory Order on phthalates. Therefore there is no violation of the legislation for this ball.
[13] DIBP has a harmonised classification as Repr. 1B, i.e. the limit is 0.5% in the Danish Statutory Order on toys but 0.05% in the Danish Statutory Order on phthalates.

Sample no.	Product	Part analysed	Type	Product group	Quantified content of phthalate (weight %)	The product does not comply with the following legislation	Maximum permitted content
507	Doll with horse	Head	Toy	B	-		
		Saddle			-		
508	Swim ring	Valve	Toy	B	-		
		See-through plastic			-		
510	Beach toy	Valve	Toy	B	-		
		Green plastic	Toy	B	-		
511	Space hopper with string	String	Toy	B	-		
512	**Jump rope**	**String**	**Toy**	**B**	**DEHP (17%)**	**DK Stat. Ord. on toys**	**0.5%**
						REACH – Entry 51	**0.1%**
516	Doll	Head	toy	B	-		
517	Badminton set	Handle	Toy	A	-		
520	Doll	Head	Toy	D	-		
521	Ball	Ball	Toy	C	-		

Sample no.	Product	Part analysed	Type	Product group	Quantified content of phthalate (weight %)	The product does not comply with the following legislation	Maximum permitted content
522	Water wings	Valve	Childcare article	H	-		
		Yellow plastic	Childcare article	H	-		
523	Water wings	Valve	Childcare article	H	-		
		Plastic	Childcare article	H	-		
524	Bathing west	Valve	Childcare article	H	DBP (0.01%) NB. May be as low as 0.007 % due to uncertainty	No violation	0.1%
		Plastic	Childcare article	H	DBP (0.01%) NB. May be as low as 0.007 % due to uncertainty	No violation	0.1%
525	Bathing pool	Valve	Toy	D	-		
		Plastic	Toy	D	-		
526	Beach toy	Valve	Toy	B	DIBP (0.01%) NB. May be as low as 0.007 % due to uncertainty	No violation	0.5%
		Plastic	Toy	B	DIBP (0.01%) NB. May be as low as 0.007 % due to uncertainty	No violation	0.5%
529	Bib	Plastic	Childcare article	H	-		

Sample no.	Product	Part analysed	Type	Product group	Quantified content of phthalate (weight %)	The product does not comply with the following legislation	Maximum permitted content
530	Nursing pillow	Plastic	Childcare article	H	DEHP (0.02%) NB. May be as low as 0.014 % due to uncertainty	No violation	0.1%
573	Swim ring	Valve	Toy	D	-		
		Plastic	Toy	D	-		
574	Swim ring	Valve	Toy	D	DEHP (0.03%) NB. May be as low as 0.021 % due to uncertainty	No violation	0.5% / 0.1%
		Plastic	Toy	D	DEHP (0.02%) NB. May be as low as 0.014 % due to uncertainty	No violation	0.5% / 0.1%
575	**Swim ring**	**Valve**	**Childcare article**	**H**	**DEHP (1%)**	**REACH – Entry 51**	**0.1%**
		Plastic	**Childcare article**	**H**	**DEHP (23%)**	**REACH – Entry 51**	**0.1%**
576	Beach ball	Valve	Toy	D	DEHP (0.06%) NB. May be as low as 0.042 % due to uncertainty	No violation	0.5% / 0.1%
		Plastic	Toy	D	DEHP (0.02%) NB. May be as low as 0.014 % due to uncertainty	No violation	0.5% / 0.1%
577	Beach toy	Beach toy	Toy	D	-		

Sample no.	Product	Part analysed	Type	Product group	Quantified content of phthalate (weight %)	The product does not comply with the following legislation	Maximum permitted content
578	Snorkel	Mouth piece	Toy	B	-		
580	Flippers	Black part around the foot	Toy	B	-		
581	Snorkel	Mouth piece	Toy	B	-		
582	Water wings	Valve	Childcare article	H	-		
		Plastic	Childcare article	H	-		
588	**Bathing pool**	**Valve**	**Toy**	**D**	**DEHP (15%)** DIBP (0.06%) NB. May be as low as 0.042% due to uncertainty	**DK Stat. Ord. on toys**	**0.5% for DEHP** and DIBP
						REACH – Entry 51	**0.1% for DEHP**
		Plastic	**Toy**	**D**	**DEHP (23%)** **DNOP (0.2%)** NB. May be as low as 0.14% due to uncertainty **DINP (0.2%)** NB. May be as low as 0.014% due to uncertainty	**DK Stat. Ord. on toys**	**0.5% for DEHP**
						REACH – Entry 51	**0.1% for DEHP**
						REACH – Entry 52	**0.1% for DNOP and DINP**

Sample no.	Product	Part analysed	Type	Product group	Quantified content of phthalate (weight %)	The product does not comply with the following legislation	Maximum permitted content
589	**Doll**	**Head**	**Toy**	**B**	**DEHP (24%)**	**DK Stat. Ord. on toys**	**0.5%**
						REACH – Entry 51	**0.1%**
590	**Doll**	**Head**	**Toy**	**B**	**DEHP (28%)**	**DK Stat. Ord. on toys**	**0.5%**
						REACH – Entry 51	**0.1%**
591	**Bow with arrows**	**Suction discs**	**Toy**	**B**	**DEHP (6%)** **DIBP (22%)**	**DK Stat. Ord. on toys**	**0.5% for DEHP and DIBP**
						REACH – Entry 51	**0.1% for DEHP**
592	**Doll**	**Head**	**Toy**	**B**	**DEHP (21%)**	**DK Stat. Ord. on toys**	**0.5%**
						REACH – Entry 51	**0.1%**
593	Rubber duck	Plastic	Toy	D	-		

Sample no.	Product	Part analysed	Type	Product group	Quantified content of phthalate (weight %)	The product does not comply with the following legislation	Maximum permitted content
617	Swim ring	Mouth valve	Toy	D	DEHP (0.005%) NB. May be as low as 0.0035% due to uncertainty DIBP (0.005%) NB. May be as low as 0.0035% due to uncertainty DBP (0.02%) NB. May be as low as 0.014% due to uncertainty	No violation	0.1% for DEHP 0.05% for DIBP 0.1% for DBP
		Plastic	Toy	D	DEHP (0.005%) NB. May be as low as 0.0035% due to uncertainty DIBP (0.005%) NB. May be as low as 0.0035% due to uncertainty DBP (0.01%) NB. May be as low as 0.007% due to uncertainty	No violation	0.1% for DEHP 0.05% for DIBP 0.1% for DBP
618	Beach toy	Beach toy	Toy	D	DBP (0.005%) NB. May be as low as 0.0035% due to uncertainty	No violation	0.1%

TABLE 11
QUANTIFIED CONTENT OF PHTHALATES IN THE SELECTED PRODUCTS FOR MARKET SURVEILLANCE AND EVALUATION OF THE COMPLIANCE WITH THE APPLICABLE LEGAL REQUIREMENTS. PRODUCTS THAT FAIL TO COMPLY ARE MARKED IN BOLD.

In total, 9 of the selected products for market surveillance do not comply with the current legislation (August 2014). One product can be subject to several requirements. In these cases, the requirements of the most restrictive legislation must be met:

- 8 products do not comply with the Statutory Order on toys BEK no. 13 dated 10/01/2011.
- 8 products do not comply with the REACH Regulation no. 1907 dated 18/12/2006 – Entry 51.
- One single product does not comply with the REACH Regulation no. 1907 dated 18/12/2006 – Entry 52.
- One single product does not comply with the Statutory Order on phthalates BEK no. 855 dated 05/09/2009.

DEHP is the primary reason for the non-compliances, followed by the use of DIBP in two cases and DINP as well as DNOP in one single case where at the same time a very high level of DEHP occurs.

In total, violations of all four laws were observed for the selected products for market surveillance. In all cases, levels significantly above the limit value in the relevant legislation were found. The Chemical Inspection Service will enforce against these identified violations of the legislation.

It should be noted that in many products DOTP (dioctyl terephthalate) is used as a plasticiser. This is not a 'phthalate' in the ordinary sense, but a terephthalate, which is used as an alternative to phthalates. See Appendix 4: for more detailed analysis results.

6.2 Analysis of 'other products for children'

The 35 'other products for children' were initially analysed for the quantitative content of phthalates. If phthalates were identified, a maximum of 10 products were selected for migration analysis for release (migration) of phthalates in agreement with the Danish EPA.

6.2.1 Quantitative analyses of content

6.2.1.1 Analysis method

The products were analysed the same way as described for the analysis of products for market surveillance in section 6.1.1.

6.2.1.2 Detection limits

The quantitative detection limit is given in section 6.1.2 for seven phthalates. For the rest of the phthalates, the detection limit will be in the order of magnitude, depending on the structure of the phthalate.

6.2.1.3 Uncertainties

For uncertainties, see section 6.1.3. The same method has been used so it is in principle the same uncertainties that are applicable.

6.2.1.4 Analysis results for 'other products for children'

In the following section, the analysis results are presented for the 35 quantitative content analyses for 'other products for children'. The results are given in weight percentage. Products marked in bold are the products that contain phthalates.

Test	Part analysed	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Other	Plasticiser
Bicycle handle or handlebar tape									
C01	Black grip	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	Oil
C02	Orange grip	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	[1]	Oil
C03	Read grip	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	[1]	Oil
C04	**Outer surface, clear**	**0.8**	n.d.	n.d.	n.d.	**8[2]**	n.d.	n.d.	DOTP
C05	Read grip	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	Oil
C06	**Green grip**	n.d.	**0.005**	n.d.	n.d.	n.d.	n.d.	n.d.	Oil
C07	Green grip	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	Oil
C08	Pink grip	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	Oil
C09	**Blue grip**	n.d.	**0.002**	n.d.	n.d.	n.d.	n.d.	n.d.	Oil
C10	Blue ribbon without adhesive	0,01	n.d.	**0.005**	n.d.	n.d.	n.d.	n.d.	None
C11	**Black ribbon without adhesive**	n.d.	n.d.	n.d.	n.d.	**39**	n.d.	n.d.	**DINP**
Mobile covers or covers for tablets									
M01	**Red and clear material pooled**	**5**	n.d.	n.d.	n.d.	**0.3**	**0.2[3]**	n.d.	**DEHP +**
M02	**Red (without textile)**	**8**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**

Test	Part analysed	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Other	Plasticiser
M03	Orange material	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	None
M04	**Red and clear pooled**	**5**	n.d.	n.d.	n.d.	n.d.	**0.2**[3]	n.d.	**DEHP +**
M05	**Black and clear pooled**	**5**	n.d.	n.d.	n.d.	**0.08**	**0.6**[3]	n.d.	**DEHP +**
M06	Black material	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	None
M07	Green and white pooled	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	None
M08	Black material	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	None
M09	**Clear and unclear pooled**	**8**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**
M10	**Blue and clear pooled**	**8**	n.d.	n.d.	n.d.	n.d.	**0.2**[3]	n.d.	**DEHP**
M11	**Clear material**	n.d.	n.d.	n.d.	n.d.	n.d.	**1**[3]	n.d.	**DIDP**[3]
M12	Blue material	n.d.	0.007	n.d.	n.d.	n.d.	n.d.	n.d.	None
Children's wrist watches (watchbands)									
U01	Strap of wrist watch	n.d.	< 0.003	0.001	n.d.	n.d.	n.d.	n.d.	None
U02	Strap of wrist watch	n.d.	0.005	n.d.	n.d.	n.d.	n.d.	n.d.	None
U03	Strap of wrist watch	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
U04	Strap of wrist watch	0,01	n.d.	n.d.	[4]	n.d.	n.d.	n.d.	Citroflex
U05	Strap of wrist watch	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	None

Test	Part analysed	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Other	Plasticiser
U06	**Strap of wrist watch**	**0.5**	**7**	**0.02**	n.d.	n.d.	n.d.	n.d.	DIBP +
U07	Strap of wrist watch	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	None
U08	Strap of wrist watch	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
U09	Strap of wrist watch, outside and inside were pooled	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
U10	**Strap of wrist watch inside**	**15**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DEHP
U11	Strap of wrist watch and white coating	< 0.01	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
U12	Strap of wrist watch	0.01	0.015	0.002	n.d.	n.d.	n.d.	n.d.	DOTP

1 – IT MAY BE POSSIBLE THAT A PHTHALATE IS PRESENT, PERHAPS A COMPONENT FROM DINP, BUT THE OIL INTERFERS TOO MUCH TO PERFORM A COMPLETE IDENTIFICATION OR QUANTIFICATION OF THE SPECTRE.
2 – AS DOTP IS PRESENT, A STRONG INTERFERENCE ESPECIALLY FOR DINP OCCURS, BUT IT IS LIKELY THAT DINP IS PRESENT IN CONCENTRATIONS UP TO THE LISTED EVEN THOUGH A CONTENT OF 8% MAY BE A BIT ON THE HIGH SIDE.
3 – A SINGLE DIDP COMPONENT, PERHAPS BIS (8-METHYL-NONYL)PHTHALATE, QUANTIFIED BY USE OF DEHP ION 149, UNCERTAINTY UNKNOWN.
4 – POSSIBLE INTERFEERENCE BETWEEN DNOP AND A CITROFLEX COMPONENT, SO A CONTENT OF DNOP MAY BE POSSIBLE.

TABLE 12
QUANTIFIED CONTENT OF PHTHALATES IN THE PRODUCT GROUP 'OTHER PRODUCTS FOR CHILDREN'. THE RESULTS ARE GIVEN IN WEIGHT PERCENTAGES. THE PRODUCTS MARKED IN BOLD INDICATES THAT THE PRODUCTS CONTAIN PHTHALATES.

6.2.2 Migration analysis of selected products

In agreement with the Danish EPA, the following 10 products were selected for migration analyses to artificial sweat. The following 10 products were selected because they all contained one or more phthalates in concentrations above 1%.

- C04 – Bicycle grip in PVC
- C11 – Handlebar tape in PVC
- M01 – Waterproof cover in pocket shape for the mobile phone – to hang around the neck
- M02 – Pocket for mobile phone made of artificial leather
- M04 – Waterproof cover for mobile phone – to hang around the neck
- M05 – Waterproof cover for tablet
- M09 – Waterproof cover for mobile phone
- M10 – Waterproof cover for mobile phone
- U06 – Wrist watch in soft plastic
- U10 – Wrist watch in soft plastic

6.2.2.1 Analysis method

The used artificial sweat stimulant is described in ISO 105 E04 which has been used in connection with the ÖKO-TEX-certification and has also been used in previous projects for the Danish EPA. The sweat stimulant in ISO 105 E04 consists of 1-histidine-monohydrochloride-1-hydrate, sodium chloride, sodium dihydrogene phosphate and sodium hydroxide used for adjusting pH to pH 5.5.

The migration tests were carried out at 37 degrees C as this is close to body temperature and is used in EN-71-3 and ISO 105 E04. The stimulant was preheated prior to the addition of the products. The tests were placed in a temperature-controlled oven (37 +/- 3 degrees) by stirring in the number of hours (exposure times decided earlier in cooperation with the Danish EPA) for the three groups of 'other products for children' (see chapter 7). The following exposure times were used:

- For bicycle handles – 2 hours
- For mobile covers – 4 hours
- For wrist watches – 24 hours

A sample aimed at a total surface area of 25 cm^2 to 10 ml stimulant was used to get as high a concentration as possible. The total surface area represents a piece with dimensions 2 x 6.25 cm where both front and back contribute to the total area. The thickness is generally ignored and not included in the total exposed area because the thickness has typically been around 1 mm or less. A single test had a shape that required 60 ml of simulant. The water phase was decanted from the sample pieces and examined with solid phase micro extraction (SPME) of substances migrated to the liquid phase with 7 µm PDMS fibre after the addition of 25% w/w NaCl. DEHP-d4 was added as internal standard to each tube just before the analysis.

Calibration was carried out against DIBP, DBP and DINP as these phthalates were the only ones observed in the 35 samples for 'other products for children' at the quantitative analyses.

6.2.2.2 Detection limits

With this method, concentrations down to 0.1 µg/ml can be detected. The detection limit in µg/cm^2/h depends on the volume of the fluid and the exposure time.

The detection limits are around 1/3 of the limit of quantification and are specified in Table 13 below in section 6.2.2.4 concerning the analysis results, as for instance "< 0.12". It should be noted that the detection limit is lower for the wrist watches as a longer exposure time is used here.

6.2.2.3 Uncertainties

Uncertainties, based on determination in duplicate, are 30% relative at concentrations 10 times of the limit of quantification and above.

6.2.2.4 Analysis results

In the following section, the analysis results are presented for the 10 migration analyses. The analysis results show that migration of phthalates occurs from three out of the 10 analysed 'other products for children'. These are M02, U06 and U10 which are marked with bold in Table 13 below.

Test	Area of test (cm^2)	Migration time (hours)	Amount of phthalate that migrates ($\mu g/cm^2/h$)			
			DIBP	DEHP	DINP	Other
C04[1]	31	2	< 0.12	< 0.09	< 0.4	< 0.4
C11	25	2	< 0.02	< 0.02	< 0.08[2]	< 0.08
M01	25	4	< 0.01	< 0.01	< 0.04[3]	< 0.04
M02	**25**	**4**	< 0.01	**0.01**[4]	< 0.04	< 0.04
M04	25	4	<0.01	< 0.01[4]	< 0.04	< 0.04
M05	25	4	< 0.01	< 0.01	< 0.04	< 0.04
M09	25	4	< 0.01	< 0.01[4]	< 0.04	< 0.04
M10	25	4	< 0.01	< 0.01[4]	< 0.04	< 0.04
U06	**38**	**24**	**0.037**	< 0.001	< 0.004	< 0.004
U10	**24**	**24**	< 0.002	**0.010**	< 0.007	< 0.007

1 - THE DETECTION LIMIT FOR THIS SAMPLE IS HIGHER, DUE TO SHAPE AND CONSTRUCTION OF THE SAMPLE, WHICH MADE IT NECESSARY TO USE A HIGHER VOLUME OF ARTIFICIAL SWEAT. DOTP IS NOT OBSERVED IN THE LIQUID.
2 - TRACES OF DINP HAVE BEEN OBSERVED IN BOTH SUBSAMPELS BUT BELOW THE DETECTION LIMIT.
3 - TRACES OF DINP HAVE POSSIBLY BEEN OBSERVED IN THE TWO SUBSAMPELS.
4 - TRACES OF DEHP HAVE BEEN OBSERVED IN THESE SAMPELS. IT IS ONLY IN M20 THAT THE LEVEL WAS SIMILAR TO THE DETECTION LIMIT LEVEL.

TABLE 13
THE MIGRATION OF PHTHALATES FROM 10 SELECTED PRODUCTS FROM THE PRODUCT CATEGORY 'OTHER PRODUCTS FOR CHILDREN' BY EXPOSURE TO ARTIFICIAL SWEAT AT 37 °C. SAMPELS MARKED IN BOLD SHOWS MIGRATION ABOVE THE DETECTION LIMIT.

6.3 Products for which a risk assessment is carried out

The products from the product category 'other products for children' for which a risk assessment is carried out are the products from where a migration of phthalates was observed. These are the following products:

- M02 – A mobile cover made from artificial leather. The mobile cover is shaped like a pocket where the mobile phone can be placed when it is not used.
- U06 – A children's wrist watch with a strap made of soft plastic.
- U10 – A children's wrist watch with a strap made of soft plastic.

7. Exposure scenarios

For use in a risk assessment of the phthalates, exposure scenarios are prepared to describe the exposure of migrated phthalates from the products. Exposure to phthalates in the products will among others depends on the following parameters:

- Route of exposure
- Duration of exposure
- Frequency exposure
- Quantity of phthalates in the products
- Quantity of phthalates available to skin exposure or that migrates from the products
- Body weight
- Absorption of phthalates through skin

The parameters are described thoroughly below.

7.1 Equations of exposure calculations

To calculate the amount of phthalates which children can be exposed to if using the analysed products, the starting point is the model of dermal exposure given by ECHA. According to the REACH guidance documents on consumer exposure (ECHA, 2012a), the exposure of a substance migrating from a product can be described by the following equation:

$$D_{der} = \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{contact} \cdot T_{contact} \cdot 1000 \cdot n}{bw}$$

where

D_{der}	The dermal dose, i.e. the amount of substance which is absorbed per kilogram body weight.	mg/kg bw/day
Q_{prod}	The quantity of applied product	g
Fc_{prod}	The weight fraction of the substance in the product	-
Fc_{migr}	The rate of migration of the substance to skin per time unit	g/g
$F_{contact}$	The fraction of area with skin contact to take into account if the skin is only partially in contact with the product (standard = 1)	cm^2/cm^2
$T_{contact}$	Time of contact between the product and skin	days
n	Mean number of incidences per day	/day
bw	Body weight	kg

In this report, the results of the migration analyses are applied in the exposure scenarios (chapter 6). In this case, the result of the analysis multiplied with the area of product with contact to skin ($M_{prod} \cdot A_{prod}$) equals the total value of quantity of applied product (Q_{prod}), weight fraction of substance in product (Fc_{prod}), rate of migration of substance to skin per time unit (Fc_{migr}) and a conversion factor of 1000 mg/g, ($Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot 1000$ mg/g). In addition, the total amount of

migrated phthalate is not absorbed through the skin. Therefore, it is relevant to calculate the fraction of phthalate that is actually absorbed. The modified equation used in this report to calculate the exposure scenarios is thus:

$$D_{der} = \frac{M_{prod} \cdot A_{prod} \cdot F_{abs} \cdot T_{contact} \cdot n}{bw}$$

where

D_{der}	The dermal dose, i.e. the amount of substance which potentially can be absorbed per kilogram body weight. Later the equation takes into account the dermal absorption rate of the substance	µg/kg bw/day
M_{prod}	Migration of phthalate from product to artificial sweat	µg/cm²/hour
A_{prod}	Area of product with contact to skin	cm²
F_{abs}	Fraction of phthalate which is absorbed through skin	-
$T_{contact}$	Time of contact of the product and skin	hour
n	Mean number of incidences per day	/day
bw	Body weight	kg

As a starting point, realistic worst-case scenarios will be calculated. Hereafter, the scenarios can be refined if the risk assessments result in a potential risk. As a part of the realistic worst-case scenario, it is assumed that the measured migrations are constant during the assumed exposure time.

7.2 Elaboration of relevant exposure parameters

The analysed products in this report are addressed to children of different ages. Mobile covers can be used by children with great age diversity. Small children can borrow the mobile phones from their parents for a short time of use while older children can have their own mobile phone. As worst-case, 6-year-old children are chosen in the exposure scenarios as a mean of both younger and older children.

Wrist watches are assumed to be used by children at ages from 5 or 6 years and upwards. In the exposure scenarios, 6-year-old children are chosen because this age is a realistic worst-case scenario where the children can use both the wrist watch and the mobile covers. Furthermore, children have a lower body weight compared to older children and thus can reach a higher concentration of substances in the body when exposed to similar doses.

D_{der} is the calculated dose of phthalate that children are exposed to when using the products where phthalates migrate from. The calculated dose will be applied in the risk assessment.

M_{prod} is the amount of phthalate that is identified to migrate from the product to artificial sweat at a temperature of 37 °C. As agreed with the Danish EPA, the analysis has been performed in a certain period of time which represents a realistic worst-case exposure. Mobile covers are analysed for 4 hours and wrist watches for 24 hours, due to the assumption that children wear the wrist watches during night.

A_{prod} is the area of the product that comes into contact with skin during use. The area is determined by measurement of the size of the product and the size of a children's wrist. The following considerations are applied:

- The wrist of 6-year-old children is assumed to have a circumference of 12.7 cm which is based on American standards of different measurements of children (ASTM International, 2014).

- The area of wrist watches is assumed to be the length of the wrist multiplied with the width of the wrist watch. If the face of the watch is made of a different material, the area of this is subtracted.
  - On U06 the face of watch is placed on the watch strap. The total area of wrist watch in contact to skin is therefore 12.7 cm x 1.8 cm = 22.86 cm^2.
  - For U10 the area of watch with contact to skin is (12.7 – 2.5 cm) x 1.5 cm = 15.3 cm^2, where 2.5 cm is the length of the face of the watch.
- As realistic worst-case, mobile covers are assumed to be worn with complete skin contact to the stomach hanging in a strap around the neck. The area of product with skin contact is thus the area of one side of the cover.
  - For M02 the area of one side of the mobile cover is 12.5 x 8 cm = 100 cm^2.

F_{abs} is the fraction of migrated phthalate which is absorbed through skin. The fraction is identified in the health assessment chapter 8.2 for the two phthalates that migrate from the analysed 'other products for children'.

$T_{contact}$ is the time in hours where the children use the product. Wrist watches are assumed to be placed on the wrist day and night as a realistic worst-case scenario. Mobile covers are assumed to be used during transportation, with skin contact (stomach and/or hand) for 4 hours per day.

The mean number of incidences, **n**, where the child is in contact with the product is assumed to be 1 per day as $T_{contact}$ indicates the total use per day.

The body weight (**bw**) of a 6-year-old child applied in the exposure scenario of this report is recommended by the Nordic Exposure Group for Health (NEGh). In 2011, NEGh has reviewed standard values for use in exposure scenarios inside and outside the EU with intention to harmonise the use of values for REACH registration (Nordic Council of Ministers, 2011). In the report, the mean body weight of children for different ages is reported and compared to values for both Europe and the USA. NEGh recommends the use of the American values because they are more detailed despite Americans generally have a higher body weight than Europeans (Nordic Council of Ministers, 2011).

In the report, it appears that children at the ages 3 to < 6 years have a mean body weight of 18.6 kg with a 5% percentile of 13.5 kg and a 95% percentile of 26.2 kg (Nordic Council of Ministers, 2011). The body weight of children aged 6 to <11 years, the mean weight is reported to be 31.8 kg, with 5% and 95% percentiles of 19.7 kg and 52.2 kg respectively.

As the target group in this project is children of 6 years, and no specific mean body weight is reported for this age, the 5% percentile (19.7 kg) for the group of 6 to <11 years is used in this project.

The different parameters and values to be applied in this report are summarised in Table 14.

Product	M_{prod}	A_{prod}	F_{abs}	$T_{contact}$	Incidence (n)	Body weight
M02	Result of migration analysis, 0.01 µg DEHP/cm²/time	100 cm²	To be determined in health assessment	4 hours	1/day	19.7 kg
U06	Result of migration analysis, 0.037 µg DIBP/cm²/time	22.86 cm²	To be determined in health assessment	24 hours	1/day	19.7 kg
U10	Result of migration analysis, 0.010 µg DEHP/cm²/time	15.3 cm²	To be determined in health assessment	24 hours	1/day	19.7 kg

TABLE 14
VALUES USED IN EXPOSURE CALCULATIONS OF MIGRATION OF PHTHALATES FROM WRIST WATCHES AND MOBILE COVERS

8. Health and risk assessment

As described earlier, the purpose of this project has been to give an overview of children's exposure to phthalates with antiandrogene effects from toys, childcare articles and 'other products for children'. For toys and childcare articles, where restrictions concerning content of phthalates exist, no risk assessment will be performed. Therefore, the risk assessment carried out in this project exclusively concerns the phthalates with antiandrogen effects which are migrated from 'other products for children', i.e.:

- A health assessment of DEHP and DIBP is carried out.
- Exposure calculations are performed for the three products where these phthalates migrate from (M02, U06 and U10).
- Exposure calculations are performed for the background exposure for all phthalates with antiandrogen effects, i.e. exposure from indoor climate and food.
- A risk assessment is carried out for the migrated amount of the two phthalates in the three products in order to determine whether the content constitutes a health risk.
- A risk assessment is performed for the migrated amount of the two phthalates in the three products together with the total background exposure from phthalates with antiandrogen effects. This is carried out in order to determine whether the total exposure from phthalates with antiandrogen effects constitutes a health risk.

The method for calculation of the risk of exposure to phthalates is described in section 8.1. The health assessment of the two selected phthalates is described in section 8.2, and the exposure calculations and the risk assessment are described in section **Fejl! Henvisningskilde ikke fundet.** and 8.4 respectively.

8.1 Method for calculation of risk

Children who use the products for children surveyed in this project can be exposed to the same substance via different routes of exposure (dermally, orally and by inhalation). According to REACH guidelines (ECHA, 2012a), the exposure from the different routes of exposure is added in order to determine the total exposure. In this project, only the dermal exposure is calculated as it is assumed that children that use these 'other products for children' (wrist watches and mobile covers) are older children who do not have a tendency to place the products in the mouth. Exposure via the oral route of exposure is therefore assumed to be insignificant for the examined products and is not calculated. Likewise it is assumed that the amount of phthalate which evaporates from the products for children is insignificant and is not calculated.

$$D_{total} = D_{oral} + D_{der} + D_{inh}$$

According to the REACH guidelines for risk assessment (ECHA, 2012c), it shall be assessed in each case if a health risk exists by use of the following formula. The risk is calculated as the Risk Characterisation Ratio (RCR) by use of the Derived No Effect Level (DNEL):

$$RCR = \frac{Exposure\ (D_{total})}{DNEL}$$

If RCR > 1 (i.e. exposure is higher than DNEL, a risk exists. If RCR is < 1 the exposure is not considered to constitute a risk.

For a single substance, the total RCR for various routes of exposures is given by calculation of the RCR for each single route of exposure and finally addition of the RCR values for each route of exposure. Mathematically, this can be set up by the following equations:

$$RCR = \frac{Exposure\ (D_{total})}{DNEL} = \frac{D_{oral}}{DNEL} + \frac{D_{der}}{DNEL} + \frac{D_{inh}}{DNEL}$$

$$RCR = RCR_{oral} + RCR_{der} + RCR_{inh}$$

DNEL is calculated as described in ECHA's REACH Guidance Chapter R.8 (ECHA, 2012d) by use of the NO(A)EL value (No Observed (Adverse) Effect Level) for the substance. DNEL is the NOAEL value adjusted for differences between the experimental and the expected human exposure conditions. DNEL is calculated as the NOAEL value divided by different assessment factors (safety factors).

$$DNEL = \frac{NOAEL}{AF_1 \times AF_2 \times AF_3 \times AF_4 \times AF_5}$$

Five different types of assessment factors (AF) can be used as described in Table 15 below. The calculated DNEL values are described in the review of the substances below. The assessment factors are determined by use of the principles in the REACH guidance document (ECHA, 2012d) as listed in Table 15.

Parameter	Description	Used value
Interspecies differences	Allometric scaling Correction of differences in metabolic rate per kg body weight	4 for rats
Interspecies differences	Remaining differences interspecies uncertainties	2,5
Intraspecies differences	Intraspecies variation	10
Differences in duration of exposure	Sub-chronic to chronic If a sub-chronic study is used instead of a chronic study (which typically gives the lowest NOAEL)	2
Issues related to dose-response	LOAEL to NOAEL If LOAEL is used because no NOAEL is derived	3

TABLE 15
ASSESSMENT FACTORS (AF) FOR CALCULATION OF DNEL

8.1.1 Conversion to internal dose

When doses administered in animal studies are compared to human exposure data, it is relevant to use internal doses for both animals and humans. The internal dose is the amount of substance absorbed into the body and an absorption fraction must be used to determine such an internal dose. For the substances assessed in this project, insufficient data is available to determine internal doses in the animal studies. The ideal data material would be information of the amount of the substance

in the blood for e.g. a known oral exposure. Such data is, however, sparse for both animals and humans. In risk assessments, the internal dose in laboratory animals is often assumed to be 100% of the dose given to the animal, e.g. through the feed, if no specific data is available for the substance. In this way, an oral exposure for a substance in laboratory animal experiments can be converted to an internal dose which can be compared to a calculated human exposure by either oral or dermal exposure. The absorption fractions given in the section concerning absorption and distribution for the single substances are used. In this way, it is taken into account if only a percentage of the substance can be absorbed through human skin and will be available as the internal dose.

8.1.2 Combination effects

Exposure to different substances with the same effect (in this project several different phthalates with antiandrogen effects) from various sources is characterised as combination effects or cocktail effects. Combination effects from several substances with the same effect can be calculated as an additive effect by use of the dose-addition concept which is also used in the project from the Danish EPA "Exposure of pregnant consumers to suspected endocrine disruptors" (Andersen et al., 2012).

Therefore, the total, i.e. additive, risk is calculated by adding up the RCR values of the single substances (1 to n):

$$RCR_{total} = RCR_1 + RCR_2 + RCR_3 + \cdots + RCR_n$$

RCR_{total} is thus equivalent to the total (cumulative) risk which the children are exposed to by e.g. the whole group of phthalates with antiandrogen effects.

8.2 Health assessment of selected phthalates

Ten of the selected products for children, which were analysed for the content of phthalates in this project, contained phthalates in large amounts (see chapter 6). A migration analysis performed for these ten products revealed that the phthalates DIBP and DEHP were released from one and two of the ten 'other products for children' respectively. A health assessment is therefore carried out for DEHP and DIBP. As this project focuses on the antiandrogen effects, other health effects are only described briefly.

8.2.1 DEHP

DEHP is REACH registered so information from registration dossiers is available from the ECHA database on registered substances (ECHA RSD, 2014). A risk assessment of DEHP has been conducted by the EU Committee for Risk Assessment (RAC) (ECB, 2008). The risk assessment is used in this report to describe the health assessment of DEHP. In addition, the Annex XV dossier (ECHA, 2008) is also used. This Annex XV dossier identifies DEHP as 'substance of very high concern' under REACH based on the classification of DEHP as toxic to reproduction (Repr. 1B). Furthermore, the background document on the restriction proposal of the four phthalates DEHP, BBP, DBP and DIBP for indoor use (ECHA, 2012b) and the opinion of RAC (Committee for Risk Assessment) on this background document on the four phthalates (ECHA, 2012e) are used in this report to obtain information on health effects.

DEHP has a harmonised classification under the CLP regulation as being toxic to reproduction:

- Repr. 1B, H360 FD "May damage fertility. May damage the unborn child".

8.2.1.1 Identification and physical-chemical parameters

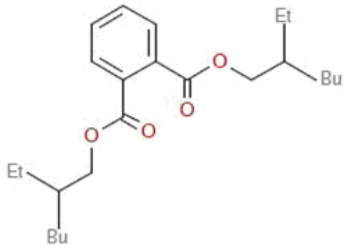
Chemical name (IUPAC)	Bis(2-ethylhexyl) phthalate
Synonyms	DEHP 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester Dioctyl phthalate (ECB, 2008)
CAS no. / EC no.	117-81-7 / 204-211-0
Molecule structure	
Molecule formula	$C_{24}H_{38}O_4$
SMILES code	O=C(OCC(CC)CCCC)C1=CC=CC=C1C(OCC(CC)CCCC)=O
Physical state	Colourless oily liquid
Molecular weight	390.6 g/mol
Melting point	-50 °C
Boiling point	230 °C (at 5 mmHg) 374.15 °C (at 1022 mbar)
Density	Between 0.95 and 1 g/ml
Vapour pressure	Reported values between 0.0000252 – 0.00086 Pa (at 25 °C) 0.0000006 – 0.000034Pa (at 20 °C)
Octanol-water partition (log Kow)	Reported values between 7.137 – 7.94
Water solubility	Insoluble < 0.1 mg/L 0.017 mg/L (at 22 °C) 0.1565 mg/L (at 20 °C)

TABLE 16
IDENTIFICATION AND PHYSICAL-CHEMICAL PROPERTIES OF DEHP
(ECHA RSD (2014) IF NOT STATED OTHERWISE)

8.2.1.2 Absorption and distribution

In the ECHA database of registered substances, several *in vivo* animal studies are listed which report the dermal absorption of DEHP. One study found a cumulative dermal absorption of DEHP of 0.064 and 0.126% from a PVC film (Deisinger et al., 1998 in ECHA RSD 2014). Other studies showed greater absorption. The differences can be explained by a direct administration to bare skin and not by administration of a PVC film from which the DEHP should migrate before dermal exposure was possible. The dermal absorption was found to be 26% when exposed to 13.2 μg/cm² for 7 days (Ng et al 1992 in ECHA RSD 2014), between 10-19% for exposure to 119-529 μg/cm² between 1 and 14 days (Chu et al 1996 in ECHA RSD 2014) and 9% when exposed to 30 mg DEHP/kg for five days (Melnick et al 1987 in ECHA RSD 2014). According to the studies, DEHP was excreted by feces and urine, but a large part of the administrated DEHP was identified in the skin of the exposed area.

The European risk assessment report (ECB, 2008) concludes the dermal absorption of DEHP to be very limited. The bioavailable percentage for both children and adults after dermal exposure is stated to be 5%. Therefore, it is decided to use **the dermal absorption fraction of 5%** in this report which is recommended by the ECB (2008) despite the fact that the studies in ECHA RSD state a larger absorption. The reason for this is that ECB (2008) concludes on a larger amount of data.

Studies on inhalation of DEHP show an absorption fraction of 75% for adults and 100% for children (ECB, 2008). The oral absorption fraction is stated to be approximately 50% for adults and 100% for children (ECB, 2008). ECHA (2008) states that new data indicates an oral absorption of 70%. In contrast RAC states that the oral absorption for adults is 100% (ECHA, 2013). ECHA (2013) concludes that an oral absorption of DEHP of 100% for both adults and children should be used. However, the oral absorption for rats is 70% (ECHA, 2013). **An oral absorption of 100% is therefore used in this project**.

DEHP is mainly metabolised in humans to MEHP (mono-(2-ethylhexyl)phthalate) which can be measured in the urine after oral exposure as reported in studies by Schmid and Schlatter (1985) and Bronsch et al. (1978) (both in ECB, 2008). Bronsch et al. (1978 in ECB (2008)) reports on 21 different metabolites measured in the urine after oral exposure while Schmid and Schlatter (1985 in ECB (2008)) reports on 12 different metabolites. Another important DEHP metabolite is 2-EH (2-ethylhexanol) as the first step of metabolism of DEHP is hydrolysis to MEHP and 2-EH (2-ethylhexanol) (ECB, 2008).

8.2.1.3 Irritation and allergy

According to ECB (2008), DEHP is slightly irritating to both skin and eyes. The observed irritation is, however, not enough to warrant a classification for irritating effects. There is not sufficient data on irritation of respiration tract to conclude if DEHP is irritating to the tract or not (ECB, 2008). DEHP is not regarded as being skin sensitising (ECB, 2008).

8.2.1.4 Acute and chronic effects

Multiple data on DEHP is available to describe the acute toxicity. ECB (2008) reports acute effects at high doses:

- LD50, oral rat: > 20,000 mg/kg bw (NTP 1982 in ECB (2008))
- LD50, oral rat: > 40,000 mg/kg bw (Noudex 1981a in ECB (2008))
- LD50, oral mouse: > 9,860 mg/kg bw (Noudex 1981b in ECB (2008))
- LD50, oral mouse: > 20,000 mg/kg bw (NTP 1982 in ECB (2008))
- LD50, dermal rabbit: ≈ 24,500 mg/kg bw (Shaffer et al 1945 in ECB (2008))

Several studies on effects after short term exposure (up to 28 days) are also reported by ECB (2008). The identified effects after oral exposure are, among others, changes in body weight gain,

testes and liver weight, histological changes in different tissues and changes in enzyme activity. All the mentioned effects are not reported in all studies or at all tested doses.

Genotoxicity and mutagenicity of DEHP are tested in several *in vitro* and *in vivo* studies (ECB, 2008). Overall, it is concluded that DEHP (and its main metabolites, MEHP and 2-EH) is not genotoxic or mutagenic.

Multiple studies mentioned in ECB (2008) report on carcinogenic effects of DEHP, and it is concluded that the majority of the studies is of good quality and therefore suitable for risk assessment. Four studies on oral exposure of mice and rats are reported. The animals were exposed to DEHP for two years in doses of 0, 100, 500, 2500 or 12500 ppm (Moore et al., 1996 in ECB 2008), 0, 100, 500, 1500, or 6.000 ppm (Moore et al., 1997 in ECB 2008), 0, 6000, or 12000 ppm (NTP 1982a in ECB, 2008) and 0, 3000 or 6.000 ppm (NTP 1982a in ECB, 2008). The lowest observed NOAEL for carcinogenic effects in these four studies was 500 ppm for both mice and rats (Moore et al. 1996 and 1997 in ECB, 2008). In the studies by NTP (1982a in ECB, 2008), no NOAEL was observed as the lowest tested dose did result in effects. Statistically significant differences between the exposure groups for hepatocellular adenomas and carcinomas were found. Apart from hepatocellular tumours, an increased incidence of liver tumours was also reported (Rao et al., 1987 in ECB, 2008), as well as mononuclear cell leukaemia (Moore et al., 1996 in ECB, 2008) and tumours in Leydigs cells (Berger 1995 in ECB, 2008). ECB (2008) concludes DEHP to be carcinogenic to mice and rats. Furthermore, they conclude that a causal relationship between carcinogenic effects and exposure to DEHP in humans is uncertain. Therefore, no classification on carcinogenic effects is recommended.

Antiandrogen effects
Several studies identify effects on the reproductive system. Below, some of these studies are summarised. Here, the focus has been to report studies relevant to determination of NOAEL values.

In a three generation study, exposure to DEHP resulted in different effects in testes (Wolfe et al., 2003 in ECB (2008)). Both male and female rats were orally exposed to DEHP in doses of 0, 1.5, 10, 30, 100, 300, 1000, 7500, or 10,000 ppm for six weeks before mating. Apart from being exposed during foetus stage, the first born generation was exposed to DEHP when lactating and later also during mating with a DEHP-exposed first generation mate. The second generation of offspring was exposed as foetuses and during lactation. A NOAEL of 100 ppm (corresponding to 8 mg/kg bw/day for the first generation and 4.8 mg/kg bw/day for the second generation) was identified for toxicity to testes (changes in testicular weight, pathological finding in testes tissue and degeneration of seminiferous tubules).

In a 13-week study, rats were exposed to DEHP in doses of 0, 0.4, 3.7, 37.6 or 375.2 or 0, 0.4, 4.2, 42.2 or 419.3 mg/kg bw/day for male and female rats respectively (Poon et al 1997 in ECHA 2014a). Significant increased liver and kidney weight was observed in the group of the largest exposure dose. Furthermore, histological changes of thyroid were also observed at this exposure level. A NOAEL value was concluded to be 3.7 mg/kg bw/day for minimal to mild Sertoli cell vacuolisation in male rats.

Pregnant rats were exposed to DEHP in doses of 0, 0.015, 0.045, 0.135, 0.405, 1.215, 5, 15, 45, 135, and 405 mg/kg bw/day during both pregnancy and during lactation (Andrade et al., 2006 in ECHA (2014a)). Effects in offspring included decreased sperm production were observed in the doses of 15 mg/kg bw/day and upwards and at the dose of 1.215 mg/kg bw/day when compared with the control group and a historical control group. The incidence of cryptorchidism (testes not in scrotum at birth) was weakly increased in exposure group of 5 mg/kg bw/day. The authors concluded NOAEL to be 1.215 mg/kg bw/day due to the incidences of cryptorchidism at 5 mg/kg bw/day. However, the Annex XV dossier document on DEHP concludes the number of incidences to be too small to determine a NOAEL value at this dose. On the other hand, the authors defend the NOAEL

value because the strain of tested rats rarely develops cryptorchidism compared to other strains of rats.

Christiansen et al. (2010 in ECHA (2014a)) examined the relation between exposure to DEHP and antiandrogen effects in pregnant rats. The rats were exposed during pregnancy and during lactating period. They were exposed to 0, 3, 10, 30, or 100 mg/kg bw/day. The results included increased number of nibbles and decreased anogenital distance in male offspring at doses of 10 mg/kg bw/day and upwards. NOAEL was determined to be 3 mg/kg bw/day.

ECB (2008) does not report on **human data** for effects on the reproduction system after exposure to DEHP. However, two studies on human exposure to DEHP with different outcomes are described. A case study on four newborns in neonatal treatment (including treatment with PVC tubes for i.e. ventilation of the child) showed that two of the four children developed symptoms of unusual lung disorder similar to those observed in hyaline membrane disease (Roth et al., 1985 in ECB (2008)). The post-mortem examination of a third child revealed DEHP in lung tissue but not in tissue of liver. The authors concluded a correlation between the observed findings and migration of DEHP from medical equipment to lung tissue.

Morbidity studies on workers of phthalate or PVC producing fabrics are also reported in ECB (2008, Thiess et al., 1978b; Thiess et al., 1978c; Milkow Milkov et al., 1973; Gilioli et al., 1978; Nielsen et al., 1985). Neurological symptoms and complaints on discomfort were reported for several workers in some of the studies; however, the studies are not suitable to assess effects or causal relations between DEHP and effects due to small cohorts and lack of knowledge on exposure.

8.2.1.5 The critical effect

The lowest observed NOAEL value for antiandrogen effects of exposure of DEHP is 1.215 mg/kg bw/day (Andrade et al 2006 in ECHA (2014a)). Due to uncertainties on the level of significance of this value (low number of cryptorchidism incidences), it is chosen not to use the value to obtain a DNEL value in this report. Instead, a NOAEL value of 4.8 mg/kg bw/day for testicular effects (Wolfe et al., 2003 in ECB (2008)) is applied. A study by Poon et al. (1997 in ECHA (2014a)) resulted in antiandrogen effects in similar range of NOAEL where histological changes of thyroid and minimal to mild Sertoli cell vacuolisation were observed with a NOAEL value of 3.7 mg/kg bw/day.

The study by Christiansen et al. (2010) was designed to test doses of 0, 3 og 10 mg/kg bw/day; therefore, it is possible that the NOAEL value could have been between the doses 3 mg/kg bw/day and 10 mg/kg bw/day. Since the study by Wolfe et al. (2003) resulted in a NOAEL value of 4.8 mg/kg bw/day, it is assumed that Christiansen et al. (2010) could have reached a higher NOAEL value if a different study design was chosen. Therefore, a NOAEL value of 4.8 mg/kg bw/day is chosen in this report which is also the chosen NOAEL value in reports of Andersen et al. (2012) as well as in ECHA (2012e and 2013). The critical effect of DEHP is antiandrogen effects.

8.2.1.6 Calculation of DNEL

The NOAEL value observed for the critical effects of DEHP is based on a developmental study on rats. Therefore, assessments factors are applied to extrapolate from rats to the general human population. The applied assessments factors are described in Table 15 and the NOAEL value is divided by a factor of 4 from rats to humans, factor 2.5 for the rest of the differences between species, and finally a factor of 10 due to intraspecies differences. In total, this results in an assessment factor of 100 and the DNEL value for antiandrogen effects is thus **48 µg/kg bw/day**.

8.2.1.7 Calculation of internal dose DNEL

Not all substances are absorbed completely after exposure. Therefore, DNEL has to be calculated into an internal dose DNEL. ECHA (2012e and 2013) states that the oral uptake of DEHP for rats is 70%. Thus, the internal dose for DNEL is **34 µg/kg bw/day**.

8.2.2 DIBP

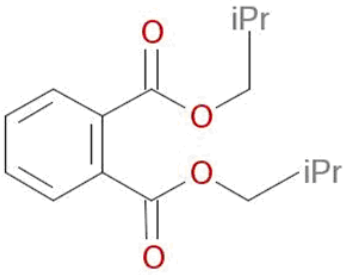
DIBP has been registered which means that information from the registration dossier is available in ECHA's database of registered substances (ECHA RSD, 2014). However, limited information is available in the database. For this reason, the Annex XV dossier (ECHA, 2009) for DIBP (which especially focuses on repeated dose toxicity as well as reproductive effects) has also been used for the health assessment of DIBP. Furthermore, the background document to the proposed restriction on the four phthalates DEHP, BBP, DBP and DIBP for indoor use (ECHA, 2012b) and the opinion from RAC concerning the background document of the four phthalates (ECHA, 2012e) have been used.

DIBP has a harmonised classification for reproductive effects:

- Repr. 1B, H360 Df "May damage the unborn child. Suspected of damaging fertility"

8.2.2.1 Identification and physical chemical parameters

The physical chemical parameters of DIBP are listed in Table 17 below.

Chemical name (IUPAC)	Diisobutyl phthalate
Synonyms	DIBP 1,2-Benzendicarboxylic acid, bis(2-methylpropyl) ester (Reference: ECHA, 2014b)
CAS nr. / EC no.	84-69-5 / 201-553-2
Molecule structure	
Molecule formula	$C_{16}H_{22}O_4$
SMILES code	C(=O)(c1 c(C(=O)OCC(C)C)cccc1)OCC(C)C
Physical appearance	Colourless viscous liquid
Molecular weight	278.35 g/mol
Melting point	-52 °C / -50 °C / -37 °C
Boiling point	320 °C (at standard pressure)
Density	1.0389 g/ml at 20 °C 1.049 g/ml at 15 °C

Vapour pressure	0.01 Pa at 20 °C 57 Pa at 20 °C (estimated value)
Octanol-water coefficient (log Kow)	4.11 at 20 °C 4.45 at 30 °C
Water solubility	Slightly soluble, i.e. 0.1 – 100 mg/L 20.3 mg/L (at 20 °C)

TABLE 17
IDENTIFICATION AND PHYSICAL CHEMICAL PROPERTIES OF DIBP
(REFERENCE: ECHA RSD (2014) IF NOT OTHERWISE STATED)

8.2.2.2 Absorption and distribution

Limited data concerning the absorption and distribution of DIBP is available. A single study is listed in ECHA RSD (2014) where DIBP has been applied to the backs of rats for seven days at a dosage of 30-40 mg/kg bw. The cumulative percentage dose excreted for 7 days was about 50–60% of the applied dose (Elsisi et al. (1989) in ECHA RSD (2014)). Another study (Scott et al. (1989) in ECHA RSD (2014)) concludes that absorption of DIBP by human skin (1.06 ug/cm²/hr) is slower than by rat skin (2.24 µg/cm²/hr). In the background document for the restriction of the four phthalates DEHP, BBP, DBP and DIBP for indoor use (ECHA, 2012b), it is assumed that the dermal absorption rate for DIBP is at the same level as DBP as these two phthalates are comparable when it comes to their structure. According to the EU risk assessment of DBP, the dermal absorption of DBP is 10% which is regarded a worst-case value (ECB, 2004). In the project for the Danish EPA "Exposure of pregnant consumers to suspected endocrine disruptors" (Andersen et al., 2012) as well as in ECHA (2012e) this **dermal absorption of 10%** is also used and therefore it will also be used in this present project for DIBP.

Data for oral absorption for DIBP has not been identified, but for other phthalates the oral absorption is considerably higher than the dermal absorption (for DEHP 100% for both adults and children) and therefore it is assumed that the oral absorption is 100% for most phthalates because of lack of data (ECHA, 2012b; ECHA, 2014b; ECHA, 2012e). Likewise, no data has been found regarding absorption via inhalation and is also assumed to be 100%.

In the body, DIBP is metabolised through hydrolysis to the monoester MIBP (mono-isobutyl phthalate) before excretion via the urine which is the major route of excretion. Little accumulation in the rat tissue was observed (ECHA, 2012b).

8.2.2.3 Irritation and allergy

The few studies reported in ECHA's database of registered substances (ECHA RSD, 2014) state that DIBP is neither irritating to skin nor eyes. However, reports of minimal skin irritation in guinea pigs do exist (ECHA, 2012b).
One study concerning skin sensitisation is reported in ECHA RSD (2004). According to this study (from 1954), DIBP is not regarded as being a skin sensitiser.

8.2.2.4 Acute and chronic effects

Some animal data for the **acute toxicity** of DIBP does exist. The data is listed below and illustrates that the acute toxicity is low as the oral LD_{50} values are above 4000 mg/kg bw:

- LD_{50}, oral rat: approx. 10,392 mg/kg bw (Study from 1959 in ECHA RSD (2014))
- LD_{50}, oral rat: 16,000-28,000 mg/kg bw (Study from 1954 in ECHA RSD (2014))
- LD_{50}, oral mouse: 4,000 mg/kg bw (Study from 1966 in ECHA RSD (2014))
- LD_{0}, dermal guinea pig: 10 ml/kg bw (Study from 1954 in ECHA RSD (2014))

In a feeding study investigating chronic effects, rats were administered the following doses during a period of four months: 0, 0.1%, 1.0% and 5% in the diet corresponding to 0, 70, 700 and 3500 mg/kg bw/day respectively. Effects in the form of significant reduction in bodyweight for the male rats were observed at the 700 mg/kg bw/day dose. Significant reduction in testes weights for the male rats and significant increase of the liver weight were observed for both sexes at the 3500 mg/kg bw/day dose. The NOEL value was 70 mg/kg bw/day (Hodge (1954) in ECHA (2009)).

Two *in vitro* bacterial gene mutation studies are listed in the registration dossier for DIBP. These two studies illustrate that DIBP is not genotoxic (Zeiger et al. (1985) and Seed (1982) in ECHA RSD (2014)). Two *in vitro* studies regarding DNA damages on human lymphocytes and human mucosa cells gave positive results but did not induce cell deaths (Kleinsasser et al. (2000) in ECHA RSD (2014)). By use of read across based on *in vivo* genotoxicity studies with DBP, it is concluded that DIBP does not produce chromosome aberration (study from 1995 in ECHA RSD (2014)). In the risk assessment of DBP (ECB, 2004), it is concluded that DPB is not regarded as being genotoxic despite one single positive study as other phthalates are not regarded as being genotoxic. A similar conclusion could be assumed to be valid for DIBP as DIBP structurally is similar to DBP, but in general it is not possible to make any conclusion regarding the genotoxic potential of DIBP.

No data is available concerning the carcinogenic properties of DIBP. Data regarding the carcinogenic properties on DBP (which structurally is very similar to DIBP) and on other phthalates is not sufficient either (ECB, 2004), which makes it difficult to conclude on the carcinogenic effects of the substance (ECHA, 2012b).

Antiandrogen effects
The most damaging effects described for DIBP concern the male reproduction system, amongst others antiandrogen effects. DIBP can also act as an endocrine disruptor via other mode of actions, but these are not described in details (ECHA, 2014b). The most important studies are described briefly below.

In a prenatal developmental study, pregnant rats were administered the doses of 0, 250, 500, 750 and 1000 mg/kg bw/day by gavage on gestation days 6 to 20. Foetuses were subject to assessment on gestation day 21. No deaths occurred among the maternal animals; however, effects were observed in the form of reduction in body weight gain at doses of 500 mg/kg bw/day and above already at gestation day 6 to 9. Pregnancy rate and the number of implantations were unaffected by treatment. The foetal body weight was significantly reduced at 500 mg/kg bw/day and above. The incidence of malformations (external, internal and skeletal) for the foetuses was significantly increased at 750 and 1000 mg/kg bw/day, and the number of liver foetuses per litter decreased at 750 mg/kg bw/day and above. The 'internal' malformations involved primarily the urinary tract, ureter and male reproductive system (including undescended testes). No effects on foetuses were observed at 250 mg/kg bw/day. For this reason, a NOAEL for developmental effects of 250 mg/kg bw/day was deducted from this study (Saillenfait et al. (2006) in ECHA RSD (2014) and ECHA (2009)).

In another prenatal study, pregnant rats were administered doses of 0, 100, 300, 600 and 900 mg/kg bw/day by gavage on gestation days 8 to 18. Foetuses were subject to assessment on gestation day 18. DIBP resulted in a reduction in maternal body weight gain and an increase in foetal mortality at the doses of 600 (17% mortality) and 900 mg/kg bw/day (59% mortality). Foetal testosterone production was significantly decreased relative to controls in the 300 (-40%), 600 (-60%) and 900 (-63%) mg/kg bw/day groups. Based on this study, a NOAEL of 100 mg/kg bw/day was determined (Howdeshell et al. (2008) in ECHA RSD (2014) and ECHA (2009)).

In a more recent prenatal study, pregnant rats were administered the doses of 0, 100, 300, 600 and 900 mg/kg bw/day by gavage on gestation day 14 to 18. Testicular testosterone production was

assessed of the 18 day old foetuses. A dose-related decrease in testosterone production was seen for DIBP (and other tested phthalates) at doses from 300 mg/kg bw/day and higher. The NOAEL value was therefore determined to be 100 mg/kg bw/day for DIBP (Hannas et al. (2011) in ECHA (2014b)).

In a postnatal study, pregnant rats were administered doses of 0, 125, 250, 500 and 650 mg/kg bw/day by gavage on gestation day 12 to 21. Changes in the reproductive system were observed until postnatal day 122. No difference in maternal body weight gain between the groups was seen and all dams delivered live pups with no effects. However, anogenital distance (the distance between anus and genitals) was significantly decreased in male pups and areolas (coloured area surrounding the nipple) and/or nipples were observed in males from dams given 250 mg/kg bw/day and above. Moreover severe malformations (e.g. absent testes) were observed in the adult males from the 500 and 650 mg/kg bw/day groups and testes weights were significantly reduced for these adult males. No NOAEL for developmental toxicity could be determined, but a LOAEL of 125 mg/kg bw/day was determined for developmental effects on the male reproduction system (Saillenfait et al. (2008) in ECHA RSD (2014) and ECHA (2009)).

ECHA (2014b) reports on several studies – including newer studies from 2010 and 2012. Common for these studies is that they all demonstrate that DIBP exhibits adverse reproductive effects. It is concluded that based on the type of effects on the male reproductive organs, an endocrine disrupting mode of action of DIBP is probable – more precisely an antiandrogen mode of action. A study from 2005 has demonstrated both oestrogen and antiandrogen activity for DIBP (Takeuchi et al. (2005) in ECHA RSD (2014)), but in general no or only a weak oestrogen activity is seen for DIBP, i.e. it is the antiandrogen activity that is the primary mode of action for DIBP.

The amount of **human data** concerning the health effects of DIBP is very limited, but ECHA (2014b) carries out read across to DBP which structurally is very similar to DIBP and other phthalates with side chains of 3-7 carbon atoms. More of these phthalates (DEHP, DBP, BBP and DINP) have shown adverse effects on the reproductive organs, genital development and nipple retention in males. Moreover, a reduction in testosterone production has been observed which indicates an antiandrogen mode of action.

In vitro studies with fetal testes tissue have shown comparable changes in germ cells whether using testes tissue from rats, mice or humans. This supports the fact that reproductive effects of phthalates are relevant to humans. In general, no data illustrates that this effect *should not be* relevant for humans (ECHA, 2014b).

8.2.2.5 The critical effect

The lowest NOEL value identified is 70 mg/kg bw/day, but at this value the effect is exclusively reduction in body weight. For the antiandrogen effects, the lowest NOAEL values identified are 100 mg/kg bw/day (the dose with an effect was 300 mg/kg bw/day) in Hannas et al. (2011) and a LOAEL value of 125 mg/kg bw/day (the dose with an effect was 250 mg/kg bw/day) in Saillenfait et al. (2008). The LOAEL value of 125 mg/kg bw/day is chosen which has also been used in other previous studies, such as 'the project on pregnant women' (Andersen et al., 2012) and ECHA (2012e). The critical effect is antiandrogen effects.

8.2.2.6 Calculation of DNEL

The LOAEL value (oral) for DIBP has been determined to 125 mg/kg bw/day and is based on a developmental study with rats. For this reason, an assessment factor (AF) of 4 for rats, a factor of 2.5 for the rest of the differences between species and a default assessment factor of 10 for intraspecies differences are applied. Moreover, an assessment factor of 3 is used for the application of a LOAEL value as no NOAEL has been determined. In total, this gives an assessment factor of

300 and the **DNEL value for DIBP is 417 µg/kg bw/day**. This value is in ECHA (2012e) rounded up to 420 µg/kg bw/day and is therefore the value used in this report.

8.2.2.7 Calculation of internal dose DNEL

As data for oral absorption of DIBP is missing, an oral absorption fraction of 1 is assumed, i.e. the internal dose DNEL is equal to the DNEL value as listed above.

8.2.3 DNEL values applied in this project

The DNEL values applied in the risk assessments of the different phthalates are listed in this section. The intern DNEL values for DEHP and DIBP are established in the two previous sections. The internal DNEL values for the rest of the phthalates with antiandrogen effects have primarily been obtained from ECHA reports (2012b, 2012e, and 2013) and from the Danish EPA 'the project on pregnant women' (Andersen et al., 2012).

Neither 'the project on pregnant women' (Andersen et al., 2012) nor ECHA (2012e) has conducted a risk assessment on the phthalate DCHP. Therefore, the applied DNEL value for this phthalate is obtained from the ECHA registration database ECHA RSD (2014). Here the DNEL value for the dermal exposure route is stated to be 250 µg/kg bw/day. The value has been obtained without assessing the use of assessment factors. A combined assessment factor of 200 is applied to reach the DNEL value of 250 µg/kg bw/day. It is assumed that the dermal and oral absorption of DCHP is 100% since no other absorption fractions are given in ECHA RSD (2014). Thus, the internal DNEL value of DCHP is 250 µg/kg bw/day.

An overview of the applied internal DNEL values for phthalates having antiandrogen effects is listed in Table 18 below.

Phthalate	Internal DNEL (µg/kg bw/day)	Reference
DEHP	34	This project and ECHA (2013)
$DINP_2$	3000	ECHA (2012b)
DBP	6.7	ECHA (2012b)
DIBP	420	This project and ECHA (2012b)
BBP	500	ECHA (2012b)
DPP	330	Andersen et al. (2012)
DNHP	500	Andersen et al. (2012)
DCHP	250	ECHA RSD (2014)

TABLE 18
OVERVIEW OF THE INTERNAL DNEL VALUES APPLIED IN THIS RISK ASSESSMENT

Furthermore, it should be noted that the DNEL values can only be calculated for substances having a threshold for the observed adverse effects. It has never been formally assessed whether with adequate scientifically certainty this can be documented for the antiandrogen effects of the phthalates classified as Repr. 1B. In 2014, Denmark proposed that the phthalates DEHP, DBP, BBP, and DIBP should be identified in the EU under REACH (article 57(f)) as endocrine disrupting

substances. If the phthalates are recognized in the EU as endocrine disrupting substances, it will afterwards be assessed if it is possible to establish a threshold for the hormone disrupting effects.

8.3 Exposure calculations

In this section, calculations are performed on exposure of children to phthalates with antiandrogen effects. The exposure to phthalates is derived from application of the analysed 'other products for children' and background exposure. The phthalates with antiandrogen effects included in the exposure calculations are (also given in Table 5):

- DEHP – di(2-ethylhexyl) phthalate
- $DINP_2$ – diisononyl phthalate
- DBP – di-n-butyl phthalate
- DIBP – diisobutyl phthalate
- BBP – butyl benzyl phthalate
- DPP – di-n-pentyl phthalate
- DNHP – di-n-hexyl phthalate
- DCHP (DCP) – dicyclohexyl phthalate

The amount of phthalates that children will be exposed to by use of 'other products for children' that emit phthalate is calculated by use of the equation given in section 7. The exposure is calculated for each of the three products (two wrist watches and one mobile cover). The combined (additive) exposure to several phthalates at the same time will furthermore be calculated. This is described thoroughly in section 8.3.1.

Children can be exposed to phthalates from other sources than the analysed 'other products for children'. Therefore, the background exposure is also presented. Background exposure of phthalates is e.g. from indoor climate and food. Furthermore, exposure can also originate from other consumer products. The exposure from these sources is thoroughly described in section 8.3.2.

8.3.1 Calculation of exposures from selected 'other products for children'

Calculation of exposure from the three analysed products, the two wrist watches (U06 and U10) and the mobile cover (M02), is performed by use of the equation given in chapter 7.1.

$$D_{der,\ U06} = \frac{0{,}037\ \frac{\mu g}{cm2 \cdot hour} \cdot 22{,}86\ cm2 \cdot 0{,}1 \cdot 24\ hours\ \cdot 1/day}{19{,}7\ kg} = 0{,}103\ \mu g/kg\ bw/day$$

Values used in the exposure calculations and results are given in Table 19.

Product	M_{prod} (µg/cm² · hour)	A_{prod} (cm²)	F_{abs} (-)	$T_{contact}$ (hours)	n (day⁻¹)	Bw (kg)	D_{der} (µg/kg bw/day)
U06 (DIBP)	0.037	22.86	0.10	24	1	19.7	0.103
U10 (DEHP)	0.01	15.3	0.05	24	1	19.7	0.009
M02 (DEHP)	0.01	100	0.05	4	1	19.7	0.010

TABLE 19
DERMAL EXPOSURE OF PHTHALATES MIGRATED FROM THE THREE ANALYSED PRODUCTS

8.3.2 Background exposure from phthalates with antiandrogen effects

Children can be exposed to phthalates from many other sources than the 'other products for children' investigated in this project. For this reason, the exposure from other 'background sources' is presented as well but **only for the phthalates with antiandrogen effects** as presented above.

It has not been the task of this project to perform a new assessment/calculation of the background exposure from phthalates with antiandrogen effects. For this reason, only the values from calculations performed in previous projects (listed below) are used:

- The project from the Danish EPA "Exposure of pregnant consumers to suspected endocrine disruptors" (Andersen et al., 2012).
- The project from the Danish EPA "Survey and Health Assessment of the exposure of 2 year-olds to chemical substances in Consumer Products" (Tønning et al., 2009).
- "Background document to the Opinion on the Annex XV dossier proposing restrictions on four phthalates" (DEHP, BBP, DBP, DIBP) (ECHA, 2012b).

8.3.2.1 Indoor climate

In the project from the Danish EPA about the 2-year olds (Tønning et al., 2009) and 'the project on pregnant women' (Andersen et al., 2012), a literature review was performed concerning the content of different phthalates in house dust and indoor air from different investigations all over the world, but primarily in the Nordic countries and Europe. The highest median values and 95% percentiles (or maximum listed values) were selected from the different investigations for the risk assessment.

Phthalates in house dust

In 'the project on pregnant women' (Andersen et al., 2012), older investigations (from 2001-2003) as well as – at the time – new data with sampling from around 2008 were identified. One of the latest investigations of measurements of phthalates in house dust, which were reported, was Danish and this investigation was at the same time the most comprehensive investigation (500 test samples from children's rooms and 150 test samples from day-care centres). For this reason, data from this Danish investigation (Langer et al., 2010) was chosen to represent measured median values and maximum values. It should be noted that most of the investigations only measured the content of the phthalates DEHP, DBP, DIBP and BBP, including the Danish investigation. Values for other phthalates were therefore taken from other investigations, if available. Therefore, values do not exist for all phthalates with antiandrogen effects.

In Table 20 below, the values used in the risk assessment in 'the project on pregnant women' (the latest of the two Danish EPA projects) are listed for phthalates in house dust. In this present project with 6 year-olds as the target group, it has been chosen only to use the values from the children's rooms and disregard the values listed for the day-care centres.

A search has been made for new literature in this present project in order to assess whether other sources and thereby other values for phthalates in house dust should be used instead of the Danish investigation. The following new investigations were identified:

- Bergh et al. (2011) is a Swedish investigation. Phthalates in house dust and indoor air in 10 Swedish homes, day-care centres and workplaces were investigated. It is not stated when the sampling has been made. Of phthalates with antiandrogen effects, DEHP, DBP, BBP and DIBP have been measured. When only looking at the values from the homes, the maximum values for house dust for BBP and DIBP are below the selected values in 'the project on pregnant women' (Table 20) whereas the values for DBP and DEHP are at the same level as the large Danish investigation, but with higher median values (of 130 and 680 µg/g respectively). The reason for this could be that the Swedish investigation only has taken 10 samples from homes, whereas the Danish investigation ('the project on pregnant women') took 500 samples. For this

reason, it was decided to stick to the values for these phthalates from the Danish investigation ('the project on pregnant women').

- Hsu et al. (2012) is a Taiwanese investigation. Phthalates from house dust from 101 children's homes were investigated. The sampling was performed in 2008/2009. Of phthalates with antiandrogen effects, DEHP, DBP and BBP were measured. The median levels for BBP in house dust were considerably lower than the values from the Danish investigation used in 'the project on pregnant women', whereas the median values for DEHP and DBP were higher (753 and 20.2 µg/g respectively). The maximum measured values are not stated and therefore it is not possible to compare these with the maximum values of the Danish investigation; however, the 75% percentile values are a factor of 5 below the Danish maximum values. As this investigation from Hsu et al. (2012) is from Taiwan, it was decided to stick to the values from the Danish investigation used in 'the project on pregnant women'.
- Bamai et al. (2014) is a Japanese investigation which has examined seven phthalates in house dust in 156 homes in 2006. Of the seven phthalates, the following phthalates have antiandrogen effects: DIBP, DBP, BBP, DEHP and DINP. Several samples have been taken from the same home, i.e. a sample from the floor and from different surfaces has been pooled into one overall sample. For DIBP the median and maximum measured values are below the values from the Danish investigation. For DBP and DEHP both median values (20.6 and 854 µg/g respectively) and maximum values (3,640 and 12,100 µg/g respectively) are higher compared to the similar values from the Danish investigation. Here the maximum values are hence about 14 and 2 times larger respectively in comparison with the values of the Danish investigation. For BBP the median values are around the same level, but the maximum value is a bit higher in the Danish investigation. This means that this Japanese investigation has found higher values for phthalates in house dust. Except for DBP where a few of the measurements are significantly higher compared to the Danish investigation, the values from the two investigations are fairly in the same order of magnitude. In this present report, it is chosen to stick to the levels measured in the Danish investigation in order to stick to the local Danish measurements which were also used in 'the project on pregnant women'. DINP was not measured in the Danish investigation. For this reason, values from a Swedish investigation were used instead. The DINP median value from this Japanese study of 95 µg/g is above the used median value from the Swedish investigation, but the maximum value is below the similar value from the Swedish investigation. For this reason, it was decided to stick to the values used in 'the project on pregnant women', i.e. the Swedish values.

Therefore the conclusion is that these new published investigations do not alter the decision taken about the values used for amounts of phthalates in house dust in 'the project on pregnant women'. Somewhat higher values have been identified for some of the phthalates (and higher values for DBP) in some of the investigations compared to the Danish investigation, but in general the values are in the same order of magnitude. In this present report, it has therefore been decided to stick to the values for content of phthalates in house dust which have been used for the risk assessment in 'the project on pregnant women', i.e. the values listed in Table 20 below. It should be noted that no data has been identified for DPP in house dust above the detection limit. For this reason, a risk assessment has only been carried out for the other phthalates with antiandrogen effects.

Source	Phthalate	Measured concentration	Comment
Phthalates in house dust			
Langer et al., 2010 **Weschler et al., 2010** (used in 'the project on pregnant women')	DEHP	Range: 12.7 – **6611 µg/g** GM: 220 µg/g Median: **210 µg/g**	During spring 2008, 500 dust samples were taken from Danish homes (bedrooms), and dust samples from 151 Danish day-care centres. All the samples were taken in Fyn. DEHP was identified in all samples both in homes and day-care centres, while DBP, DIBP and BBP were detected in more than 75% of the bedrooms and more than 90% of the day-care centres. The article compares the identified levels with some previous studies and concludes that the concentrations of BBP, DBP and DEHP are somewhat lower than in previous studies. The reasons for this, the author indicates as follows: 1) the values represent a change to use of other phthalates 2) geographic differences (different products are used in the homes of different countries) GM = Geometric Mean
	DBP	Range: < 0.18 – **253 µg/g** GM: 8.1 µg/g Median: **15 µg/g**	
	DIBP	Range: < 0.26 – **2496 µg/g** GM: 16.6 µg/g Median: **27 µg/g**	
	BBP	Range: < 0.7 – **285 µg/g** GM: 4.2 µg/g Median: **3.7 µg/g**	
	$DINP_2$	Not investigated	
	DPP	Not investigated	
	DNHP	Not investigated	
	DCHP	Not investigated	
Bornehag et al., 2004 **Bornehag et al., 2005** (used in 'the project on pregnant women')	$DINP_2$	Range: 0 – 40,667 µg/g GM: 639 µg/g Median: **41 µg/g** 95-percentile: **1930 µg/g**	346 samples of surface dust from children's room have been taken in Sweden in 2001 and 2002. Data from the same study is presented in the two sources, but Bornehag (2005) also presented results from other investigations.
Rudel et al., 2003 (described in 'the project on pregnant women')	DNHP	Range: < 0.1 – **30.6 µg/g** Median = **1.1 µg/g**	Measurements have been performed in 120 American homes in 1999-2001. The dust sample has been collected via a vacuum cleaner from 4-5 of the most used rooms of the home.

Source	Phthalate	Measured concentration	Comment
Watson, 2009 (used in 'the project on pregnant women')	DPP	Range: <1.3 µg/g - <3.3 µg/g Median = < DL	4 dust samples taken in 2 offices in the Czech Republic and an observatory on the top of a mountain and an authority building respectively. The mountain dust sample gave the value: < 1.5. Dust collected via vacuum cleaner. It has not been indicated when the samples were collected.

TABLE 20
OVERVIEW OF USED VALUES IN THE RISK ASSESSMENT FOR PHTHALATES IN HOUSE DUST. USED VALUES ARE MARKED IN BOLD. (REFERNECE: ANDERSEN ET AL., 2012).

Phthalates in indoor air

In 'the project on pregnant women' only few investigations concerning phthalates in indoor air were identified and only the phthalates DEHP, BBP, DBP and DIBP were identified in levels above the detection limit. Some of these identified investigations were relatively old. In the project, it was therefore decided to use data from the newest investigation in spite of this investigation being from Australia and being a relatively small investigation (10 samples).

In Table 21 below, the values for phthalates in indoor air used in the risk assessment in 'the project on pregnant women' are reproduced.

In this present project, a search for new literature has been made in order to assess whether other sources and thereby other values for phthalates in indoor air should be used instead of the Australian investigation. The following new investigations were identified:

- Bergh et al. (2011) is a Swedish investigation. Phthalates in house dust and indoor air in 10 Swedish homes, day-care centres and workplaces were investigated. Of phthalates with antiandrogen effects, DEHP, DBP, BBP and DIBP have been measured. When only looking at the values from the homes, both median values and maximum values for indoor air are generally higher than the Australian data used in 'the project on pregnant women' (the values are reproduced in Table 21). It is only for DIBP that the maximum value is below the maximum value from the Australian investigation, but the value is in the same order of magnitude. As the Swedish investigation may be closer to Danish conditions than the Australian data used in 'the project on pregnant women', it was therefore decided to use the Swedish data in the risk assessment in this present report.
- Takeuchi et al. (2014) is a Japanese investigation which has examined the content of 19 different phthalates in indoor air from 6 different Japanese houses in 2012. The following phthalates with antiandrogen effects were measured: DIBP, DBP, BBP, DNHP, DEHP, DCHP and DINP. However, DNHP was not identified above the detection limit. The measured values for the phthalates were generally at the same level as the Swedish investigation; however, DBP and DEHP were measured up to 4,000 and 2,400 ng/m^3 respectively in one single sample. The results of the measurements for some of the phthalates are reproduced in Table 21 below. Despite the fact that the levels for DBP and DEHP are above the levels of the Swedish investigations (Bergh et al., 2011), it was decided to use the values from the Swedish investigation in this present report because the Swedish values are expected to be closer to Danish conditions. However, the values for DCHP and DINP are used from the Japanese investigation, as no other studies, which have analysed for these two phthalates, have been identified.

Therefore, the conclusion is that these more recent published investigations do present a different picture of the amount of phthalates in indoor air. Higher values have been identified for most of the phthalates in the Swedish investigation, and more phthalates have been measured in the Japanese investigation. In this present report, it has therefore been chosen to use the new values for content of phthalates in indoor air for the risk assessment as listed in Table 21 below. It should be noted that no data for DPP and DNHP for indoor air has been identified above the detection limit. For this reason, a risk assessment is only carried out for the other phthalates with antiandrogen effects.

Source	Phthalate	Measured concentration	Comment
Phthalates in indoor air			
Boast et al., 2010 (used in 'the project on pregnant women')	DEHP	Range: 8.5 – 142.0 ng/m³ GM: 39.6 ng/m³ Median: 16.5 ng/m³	Phthalate concentration measured in indoor air in 10 homes in Melbourne, Australia. It is not stated when the sampling was performed. DNOP and DNHP are only identified in concentrations below the detection limit. The authors point out that the level of phthalates is lower in this study compared with other studies (e.g. (Rudel et al., 2003)). GM = Geometric Mean
	DBP	Range: 66.5 – 354.7 ng/m³ GM: 137.5 ng/m³ Median: 106.8 ng/m³	
	DIBP	Range: 59.6 – 686.3 ng/m³ GM: 139.5 ng/m³ Median: 61.7 ng/m³	
	BBP	Range: 0.5 – 15.2 ng/m³ GM: 6.8 ng/m³ Median: 4.9 ng/m³	
	$DINP_2$	Not investigated	
	DPP	Not investigated	
	DNHP	Range: <0.1 - <0.2 ng/m³ GM: <0.16 ng/m³	
	DCHP	Not investigated	
Bergh et al., 2011 (new source)	DEHP	Range: 92 – **530 ng/m³** GM: 208 ng/m³ Median: **200 ng/m³**	A Swedish study, which has investigated the content of phthalates in house dust and indoor air in 10 Swedish homes, day-care centres and workplaces. The following phthalates with antiandrogen effects were measured: DEHP, DBP, BBP and DIBP. It is not stated when the sampling
	DBP	Range: 300 – **2300 ng/m³** GM: 925 ng/m³ Median: **850 ng/m³**	
	DIBP	Range: 140 – **560 ng/m³**	

Source	Phthalate	Measured concentration	Comment
		GM: 296 ng/m³ Median: **270 ng/m³**	was performed.
	BBP	Range: 6,6 – **97 ng/m³** GM: 28 ng/m³ Median: **21 ng/m³**	
Takeuchi et al., 2014 (new source)	DEHP	Range: 20 – 2400 ng/m³ Median: 800 ng/m³	A Japanese study, which has investigated the content of 19 different phthalates in indoor air from 6 different Japanese houses in 2012. The following phthalates with antiandrogen effects were measured: DIBP, DBP, BBP, DNHP, DEHP, DCHP and DINP. However, DNHP was not identified above the detection limit. The measured values for some of the phthalates are reproduced.
	DBP	Range: 30 – 4000 ng/m³ Median: 1300 ng/m³	
	DINP	Range: 6 – **360 ng/m³** Median: **52 ng/m³**	
	DCHP	Range: 4 – **14 ng/m³** Median: **6 ng/m³**	

TABLE 21
OVERVIEW OF USED VALUES IN THE RISK ASSESSMENT FOR PHTHALATES IN INDOOR AIR. USED VALUES ARE MARKED IN BOLD.

Exposure calculations
Based on the selected median and maximum values for the phthalates in house dust and indoor air, exposure calculations are carried out like in the 'the project on pregnant women' by use of the equations for dust and indoor air listed below:

$$D(substance\ x)_{DUST} = \frac{Intake_{DUST} \times f(substance\ x)_{DUST} \times f(substance\ x)_{ORAL}}{BW}$$

Where

$D(substance\ x)_{DUST}$	Ingested daily dose of substance x	mg/kg bw/day
$Intake_{DUST}$	Daily intake of dust	kg/day
$f(substance\ x)_{DUST}$	Concentration of substance x in dust	mg/kg
$f(substance\ x)_{ORAL}$	Oral absorption of substance x	%
BW	Body weight	Kg

The exposure via indoor air is calculated by use of "Equation 15-2" from the REACH Guidance document, chapter R.15 "Consumer exposure estimation" (ECHA, 2012a):

$$D(substance\ x)_{inh} = \frac{F_{resp} \times C_{inh} \times IH_{air} \times T_{contact}}{BW} \times n$$

Where

$D(substance\ x)_{inh}$	Inhalatory daily dose (intake) of substance x	mg/kg bw/day
F_{resp}	Respirable fraction of inhaled substance (decimal fraction between 0 and 1)	-
C_{inh}	Concentration of substance in air of room	mg/m³
$T_{contact}$	Duration of exposure per event	hours
IH_{air}	Ventilation rate of person	m³/day
n	Number of exposures (events) per day	per day
BW	Body weight	Kg

The following parameters are used in the calculations which deviate from the used parameters in 'the project on pregnant women' and the project concerning the 2 year-olds (Tønning et al., 2008), as this present project has 6 year-olds as the target group:

- BW – 19.7 kg (Nordic Council of Ministers, 2011).
- $Intake_{DUST}$ – 50 mg/day is used. This value corresponds to the value used for adults in 'the project on pregnant women' (Andersen et al., 2012).
- $T_{contact}$ – 19 hours, corresponding to the time that people stay indoor during a day. This value is similar to the value used in the project concerning the 2 year-olds (Tønning et al., 2008), as it is assumed that 6 year-old children also stay outdoor for a large part of the day.
- IH_{air} – the respiration volume for 6 year-old children, which has been taken from ECHA (2012a). This value is 11 m³/day for 4-6 year-old children.

Based on these selected values, the exposures via the indoor climate can be calculated for the phthalates with antiandrogen effects via the indoor climate (see Table 22).

Phthalate	Used value	Measured value in dust (µg/g)	Measured value in air (ng/m³)	Exposure dust (µg/kg bw/day)	Exposure air (µg/kg bw/day)	Total exposure (µg/kg bw/day)
DEHP	Median	210	200	0.533	0.088	0.621
	Max	6611	530	16.779	0.234	17.013
$DINP_2$	Median	41	52	0.104	0.023	0.127
	95 %/Max	1930	360	4.898	0.159	5.058
DBP	Median	15	850	0.038	0.376	0.414
	Max	253	2300	0.642	1.017	1.659
DIBP	Median	27	270	0.069	0.119	0.188
	Max	2496	560	6.335	0.248	6.583
BBP	Median	3.7	21	0.009	0.009	0.019

Phthalate	Used value	Measured value in dust (µg/g)	Measured value in air (ng/m³)	Exposure dust (µg/kg bw/day)	Exposure air (µg/kg bw/day)	Total exposure (µg/kg bw/day)
	Max	285	97	0.723	0.043	0.766
DPP	Median	*Not measured*	*Not measured*	-	-	-
	Max	*Not measured*	*Not measured*	-	-	-
DNHP	Median	1.1	*Not measured*	0.003	-	0.003
	Max	30.6	*Not measured*	0.078	-	0.078
DCHP	Median	*Not measured*	6	-	0.003	0.003
	Max	*Not measured*	14	-	0.006	0.006

TABLE 22
EXPOSURE CALCULATIONS FOR THE PHTHALATES WITH ANTIANDROGEN EFFECTS VIA INDOOR CLIMATE

8.3.2.2 Food

Exposure to phthalates with antiandrogen effects from food has been described in previous studies. For use in a proposed restriction case, a background document was prepared on the phthalates DEHP, DIBP, BBP and DBP (ECHA, 2012b). The exposure was assessed for three different ages: 2-year-old, 6/7-year-old children and adults. The exposure of the 2-year-old children and adults originates from projects by the Danish EPA (Tønning et al., 2009; Andersen et al., 2012). The three reports all review the existing literature on exposure to phthalates in food and summarise the relevant exposure values used in the respective reports. The values used in this project are given in Table 23.

	Background exposure to phthalates from food (µg/kg bw/day)					
Age	**6/7-years**	**6/7-years**	**Adults**	**Adults**	**2-years**	**2-years**
Study	**ECHA, 2012b**	**ECHA, 2012b**	**Andersen et al., 2012**	**Andersen et al., 2012**	**Tønning et al., 2009**	**Tønning et al., 2009**
Statistics	**Median**	**95 percentile**	**Median**	**High intake**	**Median**	**Max**
DEHP	**11**	**16**	1.2	2.2	8.6	44
$DINP_2$	-	-	0.45	1.4	**0**	**10**
DBP	**3.5**	**10**	0.26	1.4	8.2	22
DIBP	**0.2**	**1.0**	0.6	2.1	0.48	2.4
BBP	**2.4**	**0.8**	0.2	0.4	0.8	9
DPP	-	-	0	0	-	-
DNHP	-	-	0	0	-	-
DCHP	-	-	-	-	-	-

TABLE 23
BACKGROUND EXPOSURE TO PHTHALATES WITH ANTIANDROGEN EFFECTS FROM FOOD. VALUES APPLIED IN THIS PROJECT ARE MARKED IN BOLD.

Only the background document (ECHA, 2012b) reports the exposure level of phthalates specifically for the age group of relevance in this project. However, only the phthalates DEHP, DIBP, BBP and DBP are assessed in the report. The two Danish EPA reports on the 2 year-old children (Tønning et al., 2009) and 'the project on pregnant women' (Andersen et al., 2012) deal with an additional phthalate with antiandrogen effects (DINP). However, the exposure is not given for 6 year-old children.

As seen in Table 23, data only exists for five of the eight reported phthalates, which are identified to have antiandrogen effects (according to Table 5). DNHP, DPP and DCHP are not allowed to be used in food contact materials (Andersen et al., 2012; Regulation No. 10, 2011). Therefore, an exposure to these three phthalates from food is not expected.

When calculating the background exposure to phthalates from food, data on the 6/7-year-old children (ECHA, 2012b) is used. The references used in the ECHA report are two studies (Müller et al., 2003 and Wormuth et al., 2007) which both have exposures for age groups (4-10 years and 7-14 years respectively) that can represent 6 year-old children. In this project, this data is used to describe the exposure to phthalates from food of 6 year-old children. Data on children of 2-years and pregnant women is not chosen because these two groups have a higher or lower intake of food respectively, compared to 6 year-old children. However, it should be noted that the used data is based on a body weight for the 6 year-old children, which is slightly different than used in this present project.

The median value and the 95% percentile of BBP originate from two different references in ECHA (2012b). Therefore, the median value is listed to be higher than the 95 % percentile in Table 23.

Since the ECHA report (2012b) only concerns the four phthalates, the exposure levels for DINP from the project on 2 year-old children (Tønning et al., 2009) are used. It is assumed that the exposure levels for 2 year-old children are closer to the real levels of 6 year-old than for pregnant women. However, the exposure to DINP can therefore be overestimated.

The values used for the background exposure to phthalates with antiandrogen effects from food are marked in bold in Table 23. It should be noted that the data on exposure from food is published before 2008. In this year, a regulation setting limit values for phthalates in food contact materials came into force. Therefore, it can be assumed that the background exposure from food is overestimated compared to the level in food today. However, new data is not available (ECHA, 2012b). As stated in ECHA (2012b), phthalates are still expected to be present in food as phthalates because of use in articles can enter environmental compartments and thereby end up in food. No data which estimates this environmental pollution from phthalates in food is available.

8.3.2.3 Other consumer products

In addition to background exposure from indoor climate and food, 6 year-old children can be exposed to phthalates from other consumer products than the analysed products. Appendix 2: is a list of products (toys, child care products, and 'other products for children') where a content of phthalates has been identified.

In the previous projects by the Danish EPA (Tønning et al., 2009 and Andersen et al., 2012) and the ECHA background report on the four phthalates (ECHA, 2012b), exposure calculations and assessments have been performed to establish which phthalates the target group are exposed to, and from which products the identified phthalates originate. Examples of consumer products relevant for 6 year-old children identified in these three reports are (ECHA, 2012b):

- Plastic sandals/clogs – migration of DBP has been identified in products for 6 year-old children. DEHP and DIBP have been identified in similar products addressed for different age groups (2 year-old children and adults).
- Exercise balls – migration of DIBP has been identified.
- Shower curtains – migration of DEHP has been identified.
- Oil cloth – migration of DEHP has been identified.
- Water wings – migration of DEHP has been identified.
- Bathing pool – migration of DEHP has been identified.
- School bags/toy bags – migration of DEHP has been identified.
- Erasers – migration of DEHP has been identified.

Among others, many of the listed consumer products are the reason why it is possible to identify phthalates in the indoor climate.

From the list above, intake of eraser (by chewing) is considered to be the largest contributor to the exposure of phthalates. The study on phthalate exposure from eraser is of an earlier date (Svendsen et al., 2007). Today, it assumed that lower levels of phthalates content in erasers for school children exist. Apart from erasers, plastic sandals are the largest contributor to the exposure to phthalates from the listed consumer products.

In Table 24, exposures of phthalates to 6/7 year-old children from other consumer products are listed (ECHA, 2012b). It should be noted that in the background document a different body weight is used for the 6/7 year-old children. In ECHA (2012b) the body weight of a 6/7 year-old child is stated to be 23.1 kg, while in this project the body weight used is 19.7 kg (Nordic Council of Minister, 2011). Furthermore, in ECHA (2012b), the exposure calculations are only performed on

DEHP, DIBP, BBP and DBP whereas in this present project the calculations have been performed on all phthalates identified to have antiandrogen effects. Thus, the data in Table 24 is only listed in order to indicate the extent of phthalate exposure from a single consumer product.

Consumer product	Exposure to DEHP (µg/kg bw/day)	Exposure to DIBP (µg/kg bw/day)	Exposure to DBP (µg/kg bw/day)
Plastic sandals (median exposure)	1.872		
Plastic sandals (worst case exposure)			3.911
Bathing pool	0.381		
Exercise ball		1.013	
Eraser*	15.8		

* BASED ON ORAL EXPOSURE WHEN CHEWING ON AN ERASER WITH A LARGE CONTENT OF PHTHALATE

TABLE 24
EXAMPLES OF DERMAL EXPOSURE OF SELECTED PHTHALATES IN SELECTED CONSUMER PRODUCTS (ECHA, 2012B)

8.4 Risk assessment

In this risk assessment, the calculated dermal exposure is compared with the internal DNEL. The internal DNEL values for the eight phthalates are given in section 8.2.3.

The calculated RCR values for the eight phthalates which have antiandrogen effects are given in the following sections for the chosen 'other products for children' and background exposure (indoor climate and food) respectively.

8.4.1 Risk assessment of the selected 'other child products'

The risk of antiandrogen effects by use of the three analysed products is calculated by use of the equation in section 8.1. As an example, the RCR value of the watch strap U06 is:

$$RCR, U06 = \frac{0{,}103\ \mu g/kg\ bw\ /day}{420\ \mu g/kg\ bw\ /day} = 0{,}0002$$

The results of the calculations of the three products are given in Table 25. The RCR values are all well below 1. Therefore, the use of these three analysed products by 6 year-old children does not result in a health risk of antiandrogen effects in a worst case exposure scenario. The exposure duration was 24 or 4 hours for wrist watches and mobile cover respectively. Most children of the age of 6 years will probably be exposed for a shorter time.

Product	D_{der} (µg/kg bw/day)	DNEL (µg/kg bw/day)	RCR
U06 (DIBP)	0.103	420	0.0002
U10 (DEHP)	0.009	34	0.0003
M02 (DEHP)	0.010	34	0.0003

TABLE 25
RCR VALUES OF THE THREE ANALYSED PRODUCTS

8.4.2 Risk assessment of the selected 'other products for children' combined with background exposure

In the tables below, the exposure to phthalates with antiandrogen effects is given for both indoor climate and food (as previously described in Table 22 and Table 23) together with the calculated RCR values based on the internal DNEL values (Table 25). Both results for median (Table 26) and maximum (Table 27) exposure levels are given. The realistic worst-case exposure and calculated RCR values for the analysed 'other products for children' are also listed to calculate the total RCR values. Thus, the total RCR value is the risk of exposure to phthalates with antiandrogen effects from 'other products for children', indoor climate and food.

8.4.2.1 Combined exposure – median exposure from indoor climate and food

The combined exposure and the total RCR value of all phthalates with antiandrogen effects are given in Table 26.

From Table 26, it is clear that **the combined median exposure to phthalates having antiandrogen effects from indoor climate, food and 'other products for children' does not constitute a health risk**. The combined RCR value is calculated to be 0.933. In this calculation, median values of background exposure are used in the calculation while realistic worst case exposures are used for the 'other products for children'. The phthalates DEHP and DBP are the largest contributors to the combined RCR value as the two phthalates have a joint RCR value of 0.926. For both phthalates, food is the main contributor to the exposure. In this risk assessment, the analysed 'other products for children' have no effect on the total RCR value, when children are exposed to phthalates with antiandrogen effects and the background exposure has been taken into account.

It should be noted that the combined RCR value is close to 1. Therefore, only slightly higher exposure to phthalates or other substances with antiandrogen effects will result in a RCR value exceeding 1, and thus a potential health risk could be possible when the background exposure is included.

Phtha-late	Indoor climate		Food		'Other products for children'		Total
	Exp. median	RCR median	Exp. median	RCR median	Exp.	RCR	RCR
DEHP	0.621	0.018	11	0.324	0.019*	0.0006	0.342
$DINP_2$	0.127	0.00004	-	-			0.00004
DBP	0.414	0.062	3.5	0.522			0.584
DIBP	0.188	0.0004	0.2	0.0005	0.103	0.0002	0.0012
BBP	0.019	0.00004	2.4	0.005			0.005
DPP	-	-	-	-			-
DNHP	0.003	0.00001	-	-			0.00001
DCHP	0.003	0.00001	-	-			0.00001
Sum	**-**	**0.081**	**-**	**0.851**	**-**	**0.0006****	**0.933**

* EXPOSURE TO DEHP FROM BOTH U10 AND M02
** EXPOSURE FROM USE OF BOTH U10 AND M02 AS IT IS ASSUMED THAT CHILDREN DO NOT WEAR TWO WATCHES AT THE SAME TIME

TABLE 26
CALCULATED RCR VALUES FOR **MEDIAN VALUES** FOR INDOOR CLIMATE, FOOD AND 'OTHER PRODUCTS FOR CHILDREN'

8.4.2.2 Combined exposure – maximum exposure for indoor climate and food

The combined exposure and the total RCR value for all phthalates with antiandrogen effects are given in Table 27. The maximum level of exposure from indoor climate and food is used here.

From Table 27, it is clear that **the maximum exposure to phthalates with antiandrogen effects from indoor climate, food and 'other products for children' can constitute a health risk**. The total RCR value for all phthalates with antiandrogen effects is calculated to be 2.738. In this calculation, the maximum level of background exposure is used while the realistic worst-case scenario is applied for 'other products for children'. DEHP and DBP are again the largest contributors to the total RCR value. The joint RCR value of these two phthalates is 2.712. The main contributor to the exposure to DEHP and DBP is from food. Again, the 'other products for children' analysed in this project do not contribute with a RCR value which has an influence on the total RCR value.

Phthalate	Indoor climate		Food		'Other products for children'		Total
	Exp. max	RCR max	Exp. max	RCR max	Exp.	RCR	RCR
DEHP	17.013	0.500	16	0.471	0.019*	0.0006	0.972
$DINP_2$	5.058	0.002	10	0.003			0.005
DBP	1.659	0.248	10	1.493			1.740
DIBP	6.583	0.016	1	0.002	0,103	0.0002	0.018
BBP	0.766	0.002	0.8	0.002			0.003
DPP	-	-					-
DNHP	0.078	0.0002	-	-			0.0002
DCHP	0.006	0.00002	-	-			0.00002
Sum	**-**	**0.767**	**-**	**1.970**	**-**	**0.0006****	**2.738**

* EXPOSURE TO DEHP FROM BOTH U10 AND M02
** EXPOSURE FROM ONLY U10 AND M02 AS IT IS ASSUMED THAT CHILDREN WILL NOT WEAR TWO WATCHES AT THE SAME TIME

TABLE 27
CALCULATED RCR VALUES FOR THE **MAXIMUM EXPOSURE LEVELS** FOR INDOOR CLIMATE, FOOD AND 'OTHER PRODUCTS FOR CHILDREN'

It should be noted that background data on exposure to phthalates from both indoor climate and food is uncertain. All measures of phthalates in the indoor climate show great diversity among the different analyses. This indicates diversity from house to house. The use of data on exposure to phthalates from food contact materials is especially questionable. The use of phthalates in food contact materials was regulated in 2008 and therefore the data can be overestimated compared to the levels used today in food contact materials. Therefore, it is assumed that the background exposure to phthalates from especially food is lower today, but it cannot be excluded that children exposed to maximum levels of phthalates may be in risk of antiandrogen effects.

8.4.2.3 Perspectives – other consumer products

To obtain a complete overview of the risk of exposure to phthalates with antiandrogen effects, the use of other analysed consumer products (plastic sandals, shower curtain, eraser, etc.) should be taken into account in a full risk assessment. Furthermore, exposure to phthalates with antiandrogen effects from other consumer products not tested yet should be taken into account.

In Table 28, the RCR values of the selected consumer products given in Table 24 based on ECHA (2012b) are reproduced. From Table 28 it can be seen that the realistic worst-case exposure from other consumer products can result in a total RCR value of more than 1 (addition of all RCR values in Table 28 with the total RCR value in Table 26). Thus, the total exposure to phthalates with antiandrogen effects can constitute a health risk even if only the median exposure estimates (Table 26) on background exposure are applied. The reason for this is the use of single products with a large concentration of phthalates with antiandrogen effects such as plastic sandals and eraser.

Consumer product	RCR DEHP	RCR DIBP	RCR DBP
Plastic sandal (median exposure)	0.055		
Plastic sandals (worst case exposure)			0.583
Bathing pool	0.011		
Exercise ball		0.002	
Eraser*	0.465		

* BASED ON ORAL EXPOSURE WHEN CHEWING ON AN ERASER WITH A LARGE CONTENT OF PHTHALATE

TABLE 28
EXAMPLES OF RCR VALUES FOR DERMAL EXPOSURE OF CHOSEN PHTHALATES FROM CHOSEN CONSUMER PRODUCTS (ECHA, 2012B)

It should be noted that the analysis of exposure to phthalates from erasers was performed in 2007, and it is possible that the content of phthalate in erasers targeted school children is different today. The content might be lower today compared to the level in 2007. Furthermore, it is noted that the given RCR values are based on products with a large content of phthalates and the exposure calculations are realistic worst-case scenarios. Thus, the data is not generally representative but is considered to be realistic worst-cases for single consumer products.

8.5 Summary and conclusion

From the risk assessment conducted in this project, it can be concluded that phthalates with antiandrogen effects are identified in selected, analysed products for children. Furthermore, migration of the phthalates to artificial sweat has been identified. However, the amount of migrated phthalates is, in itself, not in an order of magnitude that constitutes a health risk to children who use the products.

Former studies have shown multiple applications and uses of phthalates with antiandrogen effects. Thus, the **combined exposure to phthalates with antiandrogen effects from indoor climate, food and consumer products may constitute a health risk to children in a realistic worst-case scenario.** The calculations performed in this project reveal that phthalates with antiandrogen effects (especially DEHP and DBP) may constitute a health risk to children if the combined exposure is based on maximum exposure levels for indoor climate and food in a realistic worst-case exposure scenario. However, it should be emphasised that the used exposure data for food is old and represents values from *before* a restriction concerning the use of these phthalates in food contact materials entered into force. Therefore, the exposure from food may be expected to be lower today. Likewise, investigations of phthalates in the indoor climate illustrate that large variations exist between different households.

The exposure to phthalates with antiandrogen effects does not constitute a risk to health if the median values on exposure from indoor climate and food are used in the risk assessment. However, the calculated RCR value of 0.93 is close to 1. It should be noted that the exposure to phthalates with antiandrogen effects from other consumer products than the analysed products should be included in the risk assessment.

Thus conclusion is that exposure to single phthalates from single products does not constitute a health risk to 6 year-old children. However, the combined exposure to phthalates with antiandrogen effects from several sources may constitute a health risk to children. However, the used data is uncertain. Especially, the data on food can be overestimated as the use of phthalates in food contact materials has been restricted since the data was collected. After all, the data illustrates the importance of basing the risk assessment of phthalates with antiandrogen effects on several sources in order to approach the accurate level of the risk for children.

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Appendix 1: Overview of phthalates

The following appendix contains an overview of phthalates. It is not an exhaustive list of phthalates but a list of the phthalates that have been identified during the preparation of this project.

The phthalates are listed in the table because they meet one or more of the following 'requirements':

- According to literature and statement of quantities produced, they are the most used phthalates
- They are registered in the REACH system
- They are on the Candidate list
- They have a harmonised classification or notified classification as reprotoxic (Repr. 1A, 1B or 2)
- They have antiandrogen properties or are suspected of having it

The following information is stated in Table 29:

- The classification of the phthalates is harmonised and notified respectively (the number of notifiers that have notified the classification is specified in brackets)
- The worst notified reprotoxic classification (the number of notifiers is specified in brackets)
- If the phthalates have antiandrogen effects
- If the phthalates are on the Candidate list
- If the phthalates are registered in the REACH system (per April 2014)
- If the phthalates are regulated by REACH, i.e. if for example they are limited by Annex XVII in toys and childcare articles – this is specified by the acronym "Annex XVII"
- If the phthalates are notified in articles – this is specified by the acronym "not. in art."

The phthalates are listed by ascending CAS number

Phthalate	CAS no.	Harmonised classification	Notified classification*	Reprotoxic classification (worst)	Comment**
DCP/DCHP Dicyclohexyl phthalate	84-61-7	*Proposal:* Repr. 1B, H360FD Skin Sens. 1 H317	Repr. 2, H361 Aquatic Chronic 3 (33)	Repr. 1B, H360 (1)	Antiandrogen Registered
DEP Diethyl phthalate	84-66-2		Not classified (1027)	Repr. 2, H361 (1)	Registered
DIBP Diisobutyl phthalate	84-69-5	Repr. 1B, H360Df	Repr. 1B, H360 (Df) (415)	Repr. 1B, (Df) (415)	Antiandrogen Candidate list Registered 18 not. in art.

Phthalate	CAS no.	Harmonised classification	Notified classification*	Reprotoxic classification (worst)	Comment**
DBP/DnBP Dibutyl phthalate	84-74-2	Repr. 1B, H360Df Aquatic Acute 1, H400	Repr. 1B, H360 (Df) Aquatic Acute 1, H400 (341)	Repr. 1B, H360 (262)	Antiandrogen Candidate list Registered Annex VII 19 not. in art.
DNHP[14] Di-n-hexyl phthalate	84-75-3		Not Classified (3)		Antiandrogen Candidate list
DNP Dinonyl phthalate	84-76-4		Not Classified (5)		
BOP Butyl octyl phthalate	84-78-6				Preregistered
BBP Benzyl butyl phthalate	85-68-7	Repr.1B, H360Df Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Repr. 1B, H360 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 (323)	Repr. 1A, H360 (1)	Antiandrogen Candidate list Registered Annex VII 4 not. in art.
DEHP Bis(2-ethylhexyl) phthalate, di-(2-ethylhexyl) phthalate	117-81-7	Repr. 1B, H360FD	Repr. 1B, H360FD (302) Repr. 1B, H360 (252)	Repr. 1A, H360FD (3)	Antiandrogen Candidate list Registered Annex VII 123 not. in art.
DMEP Bis(2-methoxyethyl) phthalate	117-82-8	Repr. 1B, H360Df	Repr. 1B, H360 (Df) (262)	Repr 1B, H360 (262)	Candidate list
DNOP Dioctyl phthalate	117-84-0		Not classified (31) Aquatic Chronic 4 (23)	Repr. 2, H361 (5)	**NOT** antiandrogen Annex VII
DTDP Ditridecyl phthalate	119-06-2		Not Classified (320)		

[14] Has the same abbreviation as diheptyl phthalate with CAS 3648-21-3 (CPSC, 2010)

Phthalate	CAS no.	Harmonised classification	Notified classification*	Reprotoxic classification (worst)	Comment**
DMP Dimethyl phthalate	131-11-3		Not classified (1123)	Repr. 2, H361 (1)	Registered
DPP Dipropyl phthalate	131-16-8		Repr. 2, H361 Aquatic Chronic 2, H411 (23)	Repr. 2, H361 (23)	
DAP Diallyl phthalate	131-17-9	Acute Tox. 4, H302 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Acute Tox. 4, H302 Aquatic Acute 1, H400 Aquatic Chronic 1 , H410 (214)		Registered
DnPP Di-n-pentyl phthalate	131-18-0	Repr. 1B, H360FD Aquatic Acute 1, H400	Repr.1B, H360 Aquatic Acute 1, H400 (400)	Repr. 1A, H360 (2)	Antiandrogen Candidate list
MnBP n-butyl hydrogen phthalate, monobutyl phthalate	131-70-4		Repr.1B, H360 (23)	Repr. 1A, H360 (1)	
DIPP Diisopentyl phthalate	605-50-5	Repr. 1B, H360FD Aquatic Acute 1, H400	Repr. 1B, H360FD Aquatic Acute 1, H400 (70)	Repr. 1B, H360FD (70)	Candidate list Registered
DUP Diundecyl phthalate	3648-20-2		Not Classified (54)		Registered
DNHP[15] Diheptyl phthalate	3648-21-3		Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE, H335 Repr. 2, H361 (23)	Repr. 2, H361 (23)	
BIP Butyl isobutyl phthalate	17851-53-5				Preregistered

[15] Diheptyl phthalate has the same abbreviation as dihexyl phthalate with CAS 84-75-3, (CPSC, 2010)

Phthalate	CAS no.	Harmonised classification	Notified classification*	Reprotoxic classification (worst)	Comment**
DIDP Diisodecyl phthalate	26761-40-0		Not Classified (99)		Suspected of antiandrogen effects Annex VII
DITDP[16] Diisotridecyl phthalate	27253-26-5		Not Classified (2)		Registered
DIOP Diisooctyl phthalate	27554-26-3		Repr. 1B, H360 Aquatic Chronic 4 (93)	Repr. 1B, H360 (93)	
$DINP_2$ Diisononyl phthalate	28553-12-0		Not Classified (792)		Antiandrogen Registered Annex VII
DPHP Bis(2-propylheptyl) phthalate	53306-54-0		Not Classified (133)		Registered
1,2-benzendicarboxyl acid, mixed cetyl og stearyl esters	68442-70-6		Not Classified (26)		
1,2-Benzendicarboxyl acid, benzyl C7-9-branched and linear alkyl esters	68515-40-2		Not Classified (53)		Registered
1,2-benzendicarboxyl acid, di-C7-9-branched and linear alkyl esters	68515-41-3		Not Classified (7)		
DHNUP 1,2-Benzendicarboxyl acid, di-C7-11-branched and linear alkyl esters	68515-42-4	Repr. 1B, H360Df	Repr. 1B, H360 (90)	Repr. 1B, H360 (90)	Candidate list
911P Di-C9-11 alkyl phthalate	68515-43-5		Not Classified (99)		Registered

[16] Has the same abbreviation as the phthalate with CAS 68515-47-9 (CPSC, 2010)

Phthalate	CAS no.	Harmonised classification	Notified classification*	Reprotoxic classification (worst)	Comment**
1,2-benzendicarboxyl acid, diheptyl esters, branched and linear	68515-44-6		Classification not specified (2)		
79P 1,2-Benzendicarboxyl acid, dinonyl esters, branched and linear	68515-45-7		Not Classified (4)		
DITDP[17] 1,2-Benzendicarboxyl acid, di-C11-14-branched alkyl esters, C13-rich	68515-47-9		Not Classified (85)		Registered
1,2-Benzendicarboxyl acid, di-C8-10-branched alkyl esters, C9-rich	68515-48-0		Not Classified (243)	Repr. 2, H361 (3)	Registered
1,2-Benzendicarboxyl acid, di-C9-11-branched alkyl esters, C10-rich	68515-49-1		Not Classified (378)		Registered
DIHP 1,2-benzendicarboxyl acid, dihexyl ester, branched and linear Diisohexyl phthalate	68515-50-4	*Proposals:* Repr.[18]	Repr. 2, H361 (14)	Repr. 2, H361 (14)	SVHC intention[19]
610P Di-C6-10-alkyl phthalate	68515-51-5		Not Classified (2)		Suspected of antiandrogene effects Registered
1,2-benzendicarboxyl acid, mixed decyl og lauryl and octyl diesters	70693-30-0		Not Classified (3)		
Diisobutyl hexahydro phthalate	70969-58-3		Not Classified (3)		Registered

[17] Has the same abbreviation as diisotridecyl phthalate with CAS 27253-26-5 (CPSC, 2010)
[18] A proposal of a harmonised classification as toxic to reproduction. The exact classification is not specified. http://echa.europa.eu/registry-of-submitted-harmonised-classification-and-labelling-intentions/-/substance/57/search/68515-50-4/term
[19] A proposal to include this phthalate in the Candidate list. http://echa.europa.eu/web/guest/registry-of-submitted-svhc-intentions?search_criteria=68515-50-4

Phthalate	CAS no.	Harmonised classification	Notified classification*	Reprotoxic classification (worst)	Comment**
1,2-Benzendicarboxyl acid, di-C8-10-alkyl esters	71662-46-9		Not Classified (51)		Registered
DIHP 1,2-benzendicarboxyl acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	Repr. 1B, H360D	Repr. 1B, H360	Repr. 1B, H360 (D) (4)	Candidate list
DPP 1,2-Benzendicarboxyl acid, dipentyl ester, branched and linear and linear/bis-C5-alkyl-(linear and branched) phthalate	84777-06-0	Repr. 1B, H360FD Aquatic Acute 1, H400	Repr. 1B, H360 (FD) Aquatic Acute 1, H400 (70)	Repr. 1B, H360 (FD) (70)	Candidate list
1,2-benzendicarboxyl acid, mixed hexyl og oleyl and stearyl diesters	84961-72-8		Not Classified (16)		
DIUP[20] Diundecyl phthalate, branched and linear	85507-79-5		Not Classified (19)		Registered
1,2-Benzendicarboxyl acid, di-C16-18-alkyl esters	90193-76-3		Not Classified (18)		Registered
DIUP[21] Diisoundecyl phthalate	96507-86-7		Not Classified (4)		
1,2-benzendicarboxyl acid, ditallow alkyl esters	99035-59-3		Not Classified (1)		
PIPP n-pentyl-isopentyl phthalate	776297-69-9	Repr. 1B, H360FD Aquatic Acute 1, H400	Repr. 1B, H360 (FD) Aquatic Acute 1, H400 (70)	Repr. 1B, H360 (FD) (70)	Candidate list

* THE NOTIFIED CLASSIFICATION WITH A REP-CLASSIFICATION IS SPECIFIED. THE NUMBER OF NOTIFIERS IS SPECIFIED IN BRACKETS
**THE COMMENT STATES IF THE PHTHALATES ARE REGISTERED UNDER REACH, IF THE PHTHALATES ARE ON THE CANDIDATE LIST, IF THE PHTHALATES HAVE ANTIANDROGENE EFFECTS AND IF THE PHTHALATES ARE NOTIFIED AS CANDIDATE LIST SUBSTANCES IN ARTICLES (IN SUCH CASES, HOW MANY NOTOFICATIONS) THE SIX REGULATED PHTHALATES (BY REACH ANNEX XVII) ARE MARKED WITH THE TEXT "EU LIMITED" IN THE COMMENT COLUMN.

TABLE 29
OVERVIEW OF PHTHALATES

[20]Has the same abbreviation as the diisoundercyl phthalate with CAS 96507-86-7 (CPSC, 2010)
[21] Has the same abbreviation as the diundecyl phthalate, branched and linear, with CAS 85507-79-5 (CPSC, 2010)

Appendix 2: Examples of phthalates identified in toys, childcare articles and 'other products for children'

This appendix contains three tables with examples of products for which chemical analyses have identified a content of phthalates. The three tables cover examples of products from the three product groups addressed in this project which are:

- Toys
- Childcare articles
- 'Other products for children'

Toys	Phthalates identified	Materials where the phthalates have been identified	Reference
Toy bags	DEHP: 2 – 20 %	Soft plastic	Tønning et al., 2010
Teddy bears	DBP: 0.013 %	Fabric	Tønning et al., 2009
Plastic animals	One or more of DEHP, DBP, BBP, DINP, DIDP, DNOP in concentrations above 0.1 %	Soft plastic	Öko-test 12, 2009
Toy figures	DINP: 37.29 %	Soft plastic	DEPA, 2003
Markers and pencils, erasers	Phthalates	Rubber (eraser)	Danish Consumer Council, 2011
Eraser	DEHP: 17 – 54 % DINP: 32 – 70 %	Rubber	Svendsen et al., 2007
Children masks	DEHP: > 0.1 % DINP: > 14 %	Soft plastic	Swedish Chemicals Agency, 2012
Doll	DEHP: 17 – 19 %	Soft plastic	Swedish Chemicals Agency, 2012
Children's books	DBP: 0.463 % BBP: 0.019 % DIBP: 0.226 %	Laminated cardboard	DEPA, 2003
Beach toys	Phthalates	Soft plastic, rubber	TÜV Reinland, 2010
Rocking horse	One or more of DEHP, DBP, BBP, DINP, DIDP, DNOP in concentrations above 0.1 %	Plastic	Öko-test 12, 2009

Toys	Phthalates identified	Materials where the phthalates have been identified	Reference
Play stroller	One or more DEHP, DBP, BBP, DINP, DIDP, DNOP in concentrations above 0.1 %	Plastic	Öko-test 12, 2009
Running bicycles[22], handle and saddle	DEHP DIDP DPHP	Rubber	Forbrugerkemi, 2013
Toys under 3 years	DINP (trace)	Soft plastic and rubber	Danish Consumer Council, 2010
Toys, Swedish marked	DEHP: 46 % DIBP: > 0.1 % DINP: > 0.1 %	Soft plastic, rubber	Swedish Environmental Management Unit, 2014.
Toys from the European marked	DBP, DEHP DINP: 40 %	Soft plastic and rubber	Danish Technological Institute, 2004
Radio controlled car	DEHP: 4.65 % DBP: 0.62 %	Rubber (car tire)	Rapex, 2014
Wallet from artificial leather (accessory in a play set)	DEHP: 19 % DIBP: 1.1 %	Artificial leather	Rapex, 2014
Bath toys (rubber ducks)	DEHP: 28 % DBP: 0.23 %	Rubber	Rapex, 2014
Play watch (wrist watch)	DEHP: 7.9 %	Rubber or plastic? (not described in details)	Rapex, 2014
Ball (soft)	DEHP: 16.5 %	Artificial leather? (not described in details)	Rapex, 2014
Piano	DEHP: 8.9 % in wires inside the product	Plastic/rubber wires? (not described in details)	Rapex, 2014
Cowboy west	DEHP: 25 %	Artificial leather	Rapex, 2014

[22] Bicycles are defined as a toy if the height of the saddle is under 435 mm. Bicycles for children at the age of 2 are sold with a minimum saddle height of 300 mm. Running bikes for small children are therefore defined as a toy.

Toys	Phthalates identified	Materials where the phthalates have been identified	Reference
Various plastic toys – mainly dolls, masks and beach toys	Mainly DEHP (up to about 32 %), but also DBP (up to about 9 %) and DINP (up to about 9 %) in a few products	Plastic	Rapex, 2014
Rubber ducks	DEHP: 21 %	Rubber	Rapex, 2013
Pencil case (crayons)	DEHP: 2.7 %	It is stated that it is found in the crayons	Rapex, 2013
Crayons	DEHP: 8.46 %	It is stated that it is found in the crayons	Rapex, 2013
Glitter pen	DEHP: 21-25 %	Plastic grip on the glitter pen	Rapex, 2013
Toy pistol (soft tip arrows)	DEHP: 7.24 % DBP: 2.45 %	Rubber/soft plastic (It is not stated what the soft tips is made of)	Rapex, 2013
Electronic teddy bear/doll	DEHP: 10.9 % in wires	Plastic/rubber (wires)	Rapex, 2013
Various plastic toys – mainly dolls but also ball and beach toys	Mainly DEHP (up to about 41 %), but also DIBP (up to about 29 %), DBP (up to about 13 %), DINP (up to about 27 %) and DIDP (up to about 0.5 %) in a few products	Plastic	Rapex, 2013
Slimy toys	DINP (0.18 %) and DEHP (0.008 %)	Softened plastic	Svendsen et al., 2006

TABLE 30
EXAMPELS OF PHTHALATES IDENTIFIED IN TOYS

Childcare articles	Phthalates identified	Material where the phthalate has been identified	Reference
Prams and push chairs	One or more of DEHP, DBP, BBP, DINP, DIDP, DNOP in concentrations above 0.1 %	Plastic	Öko-test 9, 2009
Cup on pacifier	DEHP: 0.03 % DINP: 1.6 %	Plastic	Tønning et al., 2008
Nursing pillows	DINP: 14.5 % DINP: 0.38 % DIBP incl. DBP: 0.007 % DINP: 23 % incl. DIDeP	Plastic cover Foam Plastic underlay Plastic underlay	Tønning et al. 2008
Nursing pillow	DEHP: 0.26 %	Soft plastic	Rapex, 2010
Nursing pillow	DINP, DPHP and DCHP (amount is not specified)	Soft plastic or textile (amount is not given)	Öko-test 3, 2013b
Baby mattresses	DUP (diundecyl phthalate): 0.00044 %	Stuffing	Tønning et al., 2008
Bedside for crib	DINP (amount is not specified)	Fabric with plastic print? (material is not specified)	Öko-test 2, 2012
Toilet seat for children	DEHP: 26 %	Plastic	Rapex, 2011
Bib	DINP: 3.1 % DIDP: 27.9 %	Plastic backside	Rapex, 2011
Bib in cotton with lining	DEHP: 0.189 %	Soft lining material	DEPA, 2003
Bib in cotton with lining	DEHP: 14.8 % DINP: 1.202 %	Soft lining material	DEPA, 2003
Baby sling	DINP: 0.18 % DEHP: 3.4 %	Straps	Rapex, 2010
Baby slings	DEP: 0.036 % DIBP: 0.012 %	Plastic print	Tønning et al., 2008
Children's tub with float	DEHP: 28.976 % DINP+DIDP: 0.226 %	Soft plastic	DEPA, 2003

Childcare articles	Phthalates identified	Material where the phthalate has been identified	Reference
Children's seat for chair	DIDP: 28 %	Soft plastic	Rapex, 2010
Children's chair	DEHP: 5.83 %	Soft plastic cover	Rapex, 2014
Children's chair	DEHP: 4.5 %	Soft plastic cover	Rapex 2013
Children's chair	DEHP: 25.75 %	Soft plastic	Rapex, 2011
Children's chair	DEHP: 7.85 %	Soft plastic cover	Rapex, 2013
Children's chair	DEHP: 4.23 %	Soft plastic	Rapex, 2013
Children's chair (high chair)	DBP and DIBP (lacquer) DEHP and DINP (artificial leather strap)	Lacquer and artificial leather	Öko-test 10, 2011
Baby crawling carpet	DEHP: 0.78 %	Plastic print on fabric? (material is not specified)	Öko-test 12, 2011
Stroller	DBP: 0.76 %	Plastic foil	Rapex, 2010
Apron for pram	DEHP: 0.004 %	Outer covering in plastic	Tønning et al., 2008
Pram	DEHP: 18.4 %	Plastic	Rapex, 2010
Pram	DEHP: 24.1 %	Soft plastic/rubber on handle	Rapex, 2010
Pram	DEHP: 1.232 %	Plastic	Rapex 2010
Combo stroller	DEHP: 22.6 %	Plastic	Rapex 2010
Combo stroller	DEHP: 14.5 %	Soft plastic/rubber on handle	Rapex, 2010
Combo stroller	DEHP: 34.7 %	Soft plastic /rubber on handle	Rapex, 2010
Combo stroller	DINP: > 0.05 %	Artificial leather (shoulder strap)	Danish Consumer Council, 2012

TABLE 31
EXAMPELS OF PHTHALATES IDENTIFIED IN CHILDCARE ARTICLES

'Other products for children'	Phthalates identified	Material where the phthalate has been identified	Reference
Artificial leather jacket	DEHP: 23 % DINP: 6.2 %	Artificial leather	Forbrugerkemi, 2009
Labels and reflexes on jackets	DEHP : 0.012 % DBP: 21.3 %	Soft plastic	Tønning et al. 2009
Labels and reflexes on mittens	DEHP: 14.7 % DINP: 8.6 %	Soft plastic	Tønning et al., 2009
Children's clothes	DBP: 0.077 % BBP: 2.2 % DEHP: 17 % DINP: 32 % DIDP: 0.2 % DEP: 0.00038 %	Plastic print	Greenpeace, 2004
Rainwear	DEHP: 5 – 5.6 % DINP: 9 %	Soft plastic, rubber	Test facts Sweden, 2012
T-shirt	DEHP: 22 %	Plastic print	SSNC, 2008b
Plastic sandals, 2-years old and 6/7-years old	DIBP, DBP, BBP, DEHP (10 – 46 % in several sandals for children)	Soft plastic, rubber	Tønning et al., nr. 107, 2010
Crocs	DIBP: 0.3 % DEHP: 0.5 % DBP: 5.1 %	Soft plastic	Tønning et al., 2009
Rubber boots	BIP: 0.04 % (butylisobutyl phthalate)	Rubber	Tønning et al., 2009
Plastic shoes	DBP: 10 % DEHP: 10 %	Soft plastic, Rubber	SSNC, 2009
Swim equipment, water wings	DEHP: 33 %	Soft plastic	Tønning et al., nr. 109, 2010
Bathing pool	DEHP: 26 %	Soft plastic	Tønning et al., nr. 109, 2010

'Other products for children'	Phthalates identified	Material where the phthalate has been identified	Reference
Oilcloth and placemats	DEHP: 13 – 25 %	Soft plastic	Tønning et al., nr. 109, 2010
Shower curtains for children	DEHP: 23 – 30 %	Soft plastic	Tønning et al., nr. 109, 2010
Children's lamps	DIBP, DBP, DEHP 0,004 – 0.21 %	Soft plastic	Tønning et al., nr. 108, 2010
Soap packaging	DEHP: 20 % DINP: 20 % DNOP: 15 % DEP: 11 %	Plastic	Tønning et al., 2009
Slip mats and figures	DEHP: 22 % DINP: High content BOP: 0.02 % (butyl octyl phthalate)	Soft plastic, rubber	Tønning et al., 2008
School bags	DEHP, DINP and DPHP (amount is not specified)	Soft plastic or rubber (not described)	Öko-test 3, 2013a
Beanbag	DEHP, DINP, DIDP and DPHP (amount is not specified)	Artificial fabric? (material is not specified)	Öko-test 9, 2013
Headphones, (Apple iPhone and iPad)	DEHP: 1.14 % DBP: 0.507 % DINP: 0.0725 % DIDP: 0.0075 %	Soft plastic around wire	Greenpeace, 2007
Gaming consoles (XBox 360, Wii, PS3)	DEHP: 27.5 % (outer cable) DINP: 10.6 % (outer cable) General level: DEHP: 0.01 – 0.09 % DIBP: 0.02 %	Soft plastic	Greenpeace, 2008
Car seat	The phthalate is seen in one car seat. Which phthalate and in which concentration is not specified.	Plastic	Danish Consumer Council, 2012a

'Other products for children'	Phthalates identified	Material where the phthalate has been identified	Reference
Car seats	DIBP and/or DEHP is observed in the cover	Print on cover?	Danish Consumer Council, 2013
Car seat	DEHP: > 0.1 %	Plastic	Swedish Chemicals Agency, 2013
Car seat	DIBP: 0.2 %	Plastic	ICRT, 2012

TABLE 32
EXAMPLES OF PHTHALATES IDENTIFIED IN 'OTHER PRODUCTS FOR CHILDREN'

Appendix 3: Phthalates registered with the highest tonnage band in REACH

Phthalate	CAS no.	Tonnage band (tons per year)
DEHP Bis(2-ethylhexyl) phthalate	117-81-7	100,000 – 1,000,000
DINP Di-"isononyl" phthalate	28553-12-0	100,000 – 1,000,000
1,2-Benzendicarboxyl acid, di-C8-10-branched alkyl esters, C9-rich (contains a large amount of DINP)	68515-48-0	100,000 – 1,000,000
1,2-Benzendicarboxyl acid, di-C9-11-branched alkyl ester, C10-rich (contains a large amount of DIDP)	68515-49-1	100,000 – 1,000,000
DMP Dimethyl phthalate	131-11-3	10,000 – 100,000
DUP Diundecyl phthalate	3648-20-2	10,000 – 100,000
DPHP Bis(2-propylheptyl) phthalate	53306-54-0	10,000 – 100,000
DBP Dibutyl phthalate	84-74-2	1,000 – 10,000
DIDP Diisodecyl phthalate	26761-40-0	Not registered. Is registered under the phthalate mixture CAS 68515-49-1.

TABLE 33
PHTHALATES REGISTERED WITH THE HIGHEST TONNAGE BAND IN THE REACH SYSTEM

Appendix 4: Results – quantitative analysis of selected products for market surveillance

Sample no.	Product	Part analysed	Positive Beilstein test	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Andre	Plasticiser
495	**Racket with ball**	**Ball**	**Yes**	**26**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**
496	Ball	Ball	Yes	n.d	n.d	n.d	n.d	25	n.d	n.d	DINP
499	Beach toy	Beach toy	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d.	DINCH
501	Space hopper	Ball	Yes	n.d	0.01	< 0.01	n.d	n.d	n.d	n.d.	
503	Plastic bucket	Handle	No	n.d	n.d	n.d	n.d	n.d	n.d	n.d	none
504	Space hopper with string	String	Yes	n.d	n.d	< 0.01	n.d	n.d	n.d	n.d	
505	Doll	Head	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d	DINCH
506	**Ball**	**Ball**	**Yes**	< 0.01	**32**	< 0.01	n.d.	n.d.	n.d.	n.d.	**DIBP**
507	Doll with horse	Head	Yes	n.d	< 0.01	< 0.01	n.d	n.d	n.d	n.d	DOTP
		Saddle	Yes	n.d	< 0.01	< 0.01	n.d	n.d	n.d	n.d	DOTP
508	Swim ring	Valve	Yes	n.d	< 0.01	< 0.01	n.d	n.d	n.d	n.d	DOTP
		See-through plastic	Yes	n.d	< 0.01	< 0.01	n.d	n.d	n.d	n.d	DOTP

Sample no.	Product	Part analysed	Positive Beilstein test	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Andre	Plasticiser
510	Beach toy	Valve	Yes	n.d	n.d	0.01	n.d	n.d	n.d	n.d	DOTP
		Green plastic	Yes	n.d	n.d	0.01	n.d	n.d	n.d	n.d	DOTP
511	Space hopper with string	String	Yes	n.d	n.d	< 0.01	n.d	n.d	n.d	n.d	DOTP
512	**Jump rope**	**String**	**Yes**	**17**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**
516	Doll	Head	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d.	DINCH + citroflex
517	Badminton set	Handle	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d	
520	Doll	Head	Yes	n.d	< 0.01	n.d	n.d	n.d	n.d	< 0.01*	DOTP
521	Ball	Ball	Yes	n.d	n.d	n.d	n.d	n.d	n.d	**	DOTP
522	Water wings	Valve	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d	DOTP
		Yellow plastic	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d	DOTP
523	Water wings	Valve	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d	DINCH
		Plastic	Yes	n.d	n.d	n.d	n.d	n.d	n.d	n.d	DOTP
524	Bathing west	Valve	Yes	n.d	n.d	0.01	n.d	n.d.	n.d.	n.d	DOTP
		Plastic	Yes	n.d	n.d	0.01	n.d	n.d.	n.d.	n.d	DOTP

Sample no.	Product	Part analysed	Positive Beilstein test	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Andre	Plasticiser
525	Bathing pool	Valve	Yes	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
		Plastic	Yes	< 0.005	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
526	Beach toy	Valve	Yes	n.d.	0.01	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
		Plastic	Yes	n.d.	0.01	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
529	Bib	Plastic	Yes	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
530	Nursing pillow	Plastic	Yes	0.02	< 0.01	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
573	Swim ring	mundventil	Yes	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
		plast	Yes	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
574	Swim ring	Valve	Yes	0.03	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
		Plastic	Yes	0.02	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
575	**Swim ring**	**Valve**	**Yes**	**1**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DINCH + **DEHP**
		Plastic	**Yes**	**23**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**
576	Beach ball	Valve	Yes	0.06	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
		Plastic	Yes	0.02	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
577	Beach toy	Beach toy	Yes	n.d.	< 0.01	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP

Sample no.	Product	Part analysed	Positive Beilstein test	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Andre	Plasticiser
578	Snorkel	Mouthpiece	No	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
580	Flippers	Black part around the foot	No	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	
581	Snorkel	Mouthpiece	Yes	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DOTP
582	Water wings	Valve	Yes	< 0.01	< 0.01	< 0.01	n.d.	n.d.	n.d.	n.d.	DOTP
		Plastic	Yes	< 0.01	< 0.01	< 0.01	n.d.	n.d.	n.d.	n.d.	DOTP
588	**Bathing pool**	**Valve**	**Yes**	**15**	0.06	n.d.	< 0.01	n.d.	n.d.	n.d.	**DEHP+**
		plastic	**Yes**	**23**	< 0.005	n.d.	0.2	0.2	n.d.	n.d.	**DEHP+**
589	**Doll**	**Head**	**Yes**	**24**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**
590	**Doll**	**Head**	**Yes**	**28**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**
591	**Bow with arrows**	**Suction disc**	**Yes**	**6**	**22**	n.d.	n.d.	n.d.	n.d.	n.d.	**DIBP + DEHP**
592	**Doll**	**Head**	**Yes**	**21**	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	**DEHP**
593	Rubber duck	Plastic	Yes	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	DINCH + citroflex

Sample no.	Product	Part analysed	Positive Beilstein test	DEHP	DIBP	DBP	DNOP	DINP	DIDP	Andre	Plasticiser
617	Swim ring	Valve	Yes	0.005	0.005	0.02	n.d.	n.d.	n.d.	n.d.	DOTP
		Plastic	Yes	0.005	0.005	0.01	n.d.	n.d.	n.d.	n.d.	DOTP
618	Beach toy	Beach toy	Yes	n.d.	< 0.005	0.005	n.d.	n.d.	n.d.	n.d.	DOTP

* TWO PROBABLY ISO- OR TEREPHTHALATES CLOSE TO DEHP, BUT BOTH AT AN ESTIMATED LEVEL BELOW 0.01%
** PROBABLY A METHYL 2-ETHYLHEXYL ESTER OF TEREPHTHALIC ACID, BUT THE PRESENCE OF A PHTHALATE COULD BE POSSIBLE. HOWEVER, IT IS NOT POSSIBLE TO DETERMINE WITHOUTH A REFERENCE SAMPLE WHICH WE COULD NOT BUY.
<0.01 = THE PHTHALATE HAS BEEN DETECTED IN THE SAMPLE, BUT THE CONTENT IS TOO LOW TO QUANTIFY PRECISELY. THE CONTENT IS BELOW 0.01%.
<0.005 = THE PHTHALATE HAS BEEN DETECTED IN THE SAMPLE, BUT THE CONTENT IS TOO LOW TO QUANTIFY PRECISELY. THE CONTENT IS BELOW 0.005%.

TABLE 34
QUANTITATIVE ANALYSES OF THE SELECTED PRODUCTS FOR MARKET SURVEILLANCE. PRODUCTS WITH A CONTENT OF PHTHALATE THAT DOES NOT COMPLY WITH THE LEGISLATION ON PHTHALATES ARE MARKED IN BOLD TEXT.

Survey and health assessment of phthalates in toys and other products for children

The purpose of the project is to provide an overview of children's exposure to phthalates with antiandrogen effects from toys, childcare articles and other products for children as well as to perform market surveillance on the requirements in legislation concerning phthalates in toys and childcare articles. Based on the survey, the Danish Environmental Protection Agency selected 34 toy products and 7 childcare articles for market surveillance. In co-operation with the Danish Environmental Protection Agency, it was decided that the 35 'other products for children', which were purchased for chemical analysis for a content of phthalates, were to be distributed on the following product types: Bicycle handles, including handlebar tape, mobile covers for smartphones and tablets as well as bags for mobiles and wrist watches (watch straps). The market surveillance showed that 9 products did not comply with applicable legislation. Out of the 35 'other products for children' which were analysed for phthalates, 10 products contained one or more phthalates in concentrations above 1 %. The conclusion of the report is that exposure to a few phthalates in single products, examined as a part of this project, does not constitute a risk but that the total exposure to more phthalates with antiandrogen effects from several different sources in a realistic worst-case scenario may constitute a health risk for 6-year-old children. A large part of the risk is due to the use of a few products with high contents of phthalates as well as assumptions that phthalates are still present in food like it was some years ago – which probably is an overestimation in relation to the real situation today.

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