ARNIKA – TOXICS AND WASTE PROGRAMME

Phthalates

in Children´s Environment

Case Studies 2007–2016

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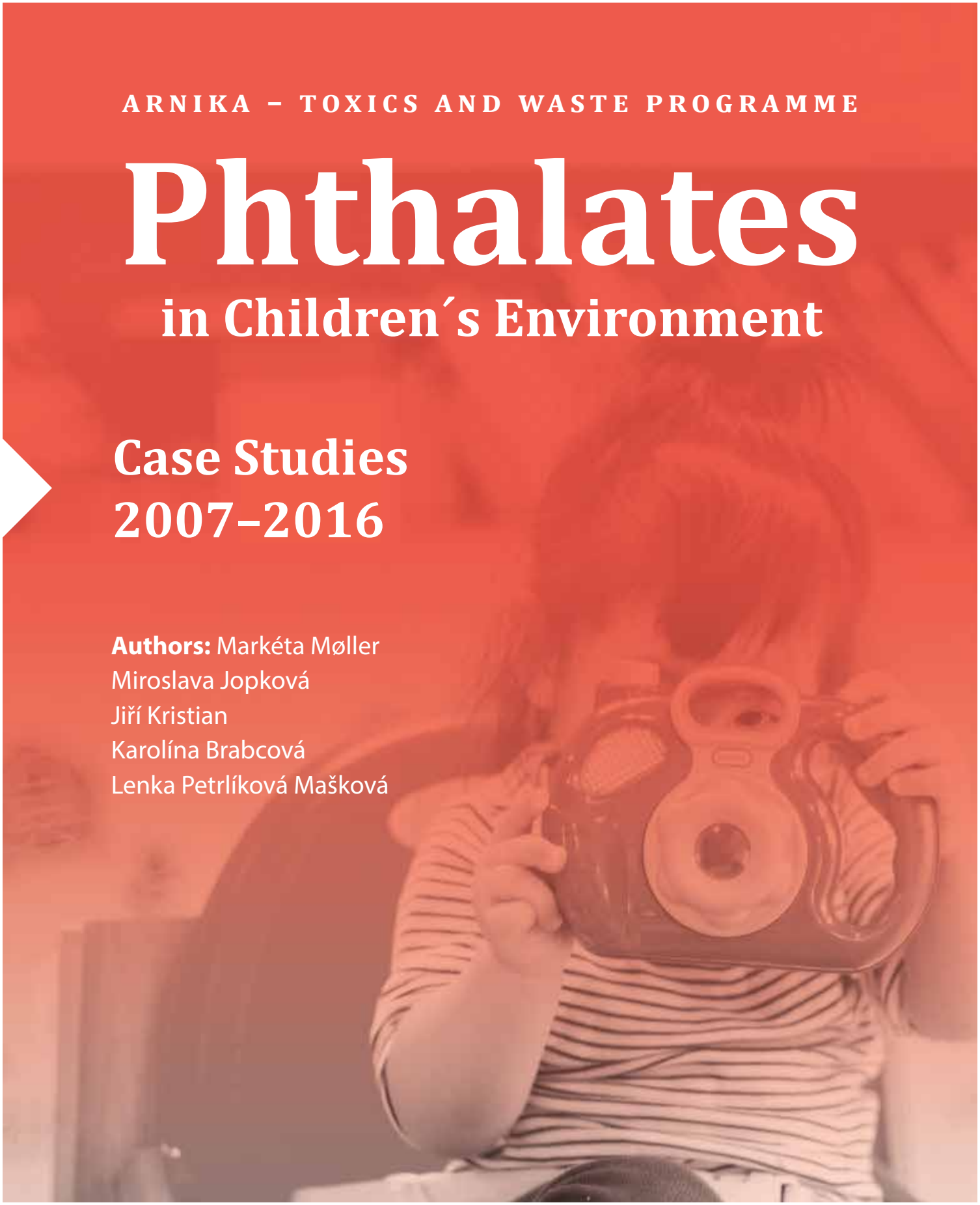

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Content

1. Introduction

The Arnika Association has studied the issue of phthalates and their presence in consumer products for many years. A special emphasis is put on products that children come into direct contact with. High numbers of goods intended for children are manufactured from plastics, specifically plasticized polyvinyl chloride (PVC), and thus, these products are a potential source of phthalates that have negative impacts on human organisms. Children, especially the youngest ones, are a group particularly sensitive to negative impact of phthalates, if they come into direct contact with them, or stay in an environment into which phthalates are released from PVC.

Phthalates enter the human organism not only through respiratory tract, but also through skin and mucous membranes. Thus, when children lick various toys, and crawl on the floor made of PVC, they are exposed to the adverse impacts even more than adults. The purpose of this case study is to summarise results of the individual analyses and studies carried out by Arnika between 2007 and 2016. Until now, many of them have been published in annexes to press releases only, or have stayed in our files in the form of reports on chemical analyses. We consider useful to provide an overall picture on the issue of phthalates in the environment and products around us, based on many years of analyses. We are aware that legislation regulating phthalate use has changed considerably since 2007, what we tried to sum up in Chapter 11 of this summary study. Simultaneously, we would like to draw attention of the readers to the fact that progress in phthalate replacements was caused just by the changes in legislation. However, often the most regulated phthalate DEHP (di(2-etylhexyl) phthalate) was substituted with new substances from this group, that are also hazardous, only, e.g. DOIP (bis(2-ethylhexyl) isophthalate).

2. Phthalates – Brief Characterization of the Substances

Phthalates (phthalic acid esters) are organic substances used as plasticizers for plastics almost a hundred years already. They find use especially in PVC manufacturing, and ensure plasticity, strength, transparency, translucency, as well as resistance, of the resulting material. In addition to PVC, phthalates may be also present in cosmetic products, adhesives, paints, and pesticides. They are a group of ca 40 substances with different chemical and toxicological properties. Phthalates with low numbers of carbon atoms have been mostly replaced with „safer" phthalates containing more than 6 carbon atoms already. Our global aim is an effort to use other plasticizers than phthalates. They enter the environment throughout the whole lifecycle of the products: during production, use, as well as disposal. They are not firmly bound in the materials, and are released into the surrounding environment. The behaviour in the environment depends on the phthalate type. People are exposed to phthalates especially through inhalation and ingestion. Some phthalates are harmless, others toxic. The hazardous ones damage the reproductive and endocrine (hormonal) systems. The company DEZA, a.s. Valašské Meziříčí from the group Agrofert ranks among the main manufacturers of toxic phthalates in Europe (DEZA 2013).

2.1 Impacts on Human and Animal Health

Whereas some phthalates probably do not harm health and the environment, others are dangerous for human health. This concerns especially phthalates toxic to reproduction, and, thus ranked among CMR substances[1] (Schettler, Solomon et al. 2000, Lyche, Gutleb et al. 2009, BUND 2011, ECHA 2018) – benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), di(2-etylhexyl) phthalate (DEHP), bis(2-methoxyethyl) phthalate (DMEP), diisobutyl phthalate (DIBP). The main hazard connected with these substances lies in their negative impacts on the endocrine (Main, Mortensen et al. 2006, Swan 2008) and reproductive systems (ECHA 2018, ECHA 2019). The list of the nine phthalates found in the analysed samples most often, and their main impacts on human health, are shown in Table 1.

Scientific studies proved relations between certain phthalates and reproductive toxicity (Jurewicz and Hanke 2011), asthma in children (Jaakkola and Knight 2008, Bornehag and Nanberg 2010, Braun, Sathyanarayana et al. 2013), and also developmental disorders (Braun, Sathyanarayana et al. 2013), such as the ADHD syndrome, characterized by attention deficit and hyperactivity (Kim, Cho et al. 2009, Froehlich, Anixt et al. 2011, Jurewicz and Hanke 2011). A longitudinal study carried out in the USA proved impacts of phthalates on neurobehavioral development of children. The study of the Mount Sinai School of Medicine in New York, lasting nine years, showed higher incidence of aggression, emotional instability, attention deficits, and depressions. The researchers measured amounts of phthalates, and their metabolites, in urine of mothers in the third trimester. If higher

[1] CMR substances - Carcinogens, mutagens and/or reproductive toxicants. More information about CMR substances is available at https://echa.europa.eu/-/chemicals-in-our-life-chemicals-of-concern-svhc.

amounts of phthalates were detected in their urine, their children showed behavioural disorders more often than in the case of mothers with low phthalate concentrations (Engel, Miodovnik et al. 2009). A further study, carried out by Swedish doctors, found that children exposed to higher phthalate concentrations, measured in dusts from their households, were more susceptible to allergies, eczema, and asthma (Bornehag and Nanberg 2010). Phthalate impacts on liver, kidneys, and lungs, and on blood coagulation, cannot be neglected, too. Impacts of phthalates on human health have to be assessed individually, because they differ in the individual phthalates (Válek and Petrlík 2014).

Table 1: Characterization of the nine most common phthalates. Adopted from BUND (2011), and completed.

Name of phthalate	Abbreviation	Health Effects	CAS number
di(2-etylhexyl) phthalate (synonym: bis(2-etylhexyl) phthalate)	DEHP	Toxic to reproduction, causes allergies and asthma	117-81-7
dibutyl phthalate	DBP	Toxic to reproduction, toxic to development	84-74-2
diisodecyl phthalate	DIDP	Damage to liver	26761-40-0
benzyl butyl phthalate	BBP	Damage to liver	85-68-7
diisononyl phthalate	DINP	Damage to liver, causes allergies and asthma, toxic to reproduction *	28553-12-0
diisobutyl phthalate	DIBP	Toxic to reproduction, toxic to development	84-69-5
di-n-octyl phthalate	DNOP	Damage to liver **	117-84-0
dipentyl phthalate	DPP	Toxic to reproduction, toxic to development ***	131-18-0
bis(2-ethylhexyl) isophtalate	DOIP	Toxic to reproduction ****	137-89-3
bis(2-methoxyethyl) phthalate	DMEP	Toxic to reproduction *****	117-82-8

* Proved in mice (Hannas, Lambright et al. 2012), but it is not ranked among reproductive toxins according to ECHA (ECHA 2020a)

** Proved in mice (Poon, Lecavalier et al. 1997, ECHA 2010)

*** Source: (Hannas, Furr et al. 2011, ECHA 2020)

**** Source: (ECHA 2019)

***** Source: (ECHA 2019a)

3. Methods

Analytical analyses of phthalate contents have been carried out by the Institute for Testing and Certification in Zlín, the Central Laboratory of the University of Chemistry and Technology in Prague, the National Reference Laboratory for Persistent Organic Pollutants (POPs), Department of the Health Institute in Ostrava, and the Health Institute in Ústí nad Labem. The hand-held X-ray spectrometer Niton XL3t operated by trained Arnika employees was used for preliminary testing, to distinguish PVC products from non-PVC ones. In some cases, heavy metal analyses formed also part of the testing. These analyses were carried out by the Central Laboratory of the University of Chemistry and Technology in Prague, too. More detailed explanation of the used analytical methods is the subject of the further paragraphs.

The hand-held X-ray spectrometer Niton XL3t has been used for preliminary analyses of **children footwear** (Chapter 6).

Heavy metals, specifically Pb, were analysed in **children footwear** (Chapter 6) by the Central Laboratory of the University of Chemistry and Technology in Prague, the Department of Environmental Chemistry, too**.** The used method was atomic absorption spectrometry (AAS) on a SensAA instrument (GBC Scientific Equipment, Australia). The leachate was prepared according to Decree No. 84/2001 Coll. of the Ministry of Health, on hygienic requirements for toys and products for children under 3 years of age, Annex No. 10 - leaching test on textiles and nonwovens for children products. The procedure CPSC-CH-C1001-09.3 is based on extracting a part (approx. 50 mg) of the analyzed sample of a children's toy/childcare product, with possible content of the monitored substances, into tetrahydrofuran (THF), precipitation of the dissolved PVC with hexane, and subsequent analysis of the resulting solution using gas chromatography with mass spectrometric detection (GC-MS).

The contents of phthalates in **children footwear** (Chapter 6), **„loom band" charms and „scoubidou strings"** (Chapter 7.2) and **toys and other products for children from Belarus** (Annex 13.1) were analysed by the Central Laboratory of University of Chemistry and Technology in Prague. The phthalate contents in the supplied samples were determined according to the procedure CPSC-CH-C1001-09.3 Standard Operating Procedure for Determination of Phthalates, issued by the U.S. Consumer Products Safety Commission on April 1, 2010. The procedure is based on dissolving/extracting a portion (ca 50 mg) of the analysed sample of the child toy/childcare article, that could contain the tested substances, in tetrahydrofuran (THF), precipitating the dissolved PVC with hexane, and subsequently analysing the produced solution using gas chromatography with mass spectrometry detection (GC-MS).

The presence of phthalates in **medical equipment** (Chapter 4), **childcare articles** (Chapter 5), **toys and toy packaging** (Chapter 7), **school supplies** (Chapter 8) and **wallpapers and floor coverings** (Chapter 9) was analysed by the Institute for Testing and Certification in Zlín. As part of the testing, the contents of extractable substances were determined (according to the standard ČSN EN ISO 6427), and, subsequently, the presence of phthalic acid esters was determined (according to the standard ČSN EN 14372), which was expressed as a weight percentage, based on the mass of the whole product. Identification of organic substances in the samples was performed using gas chromatography with a mass detector.

The National Reference Laboratory for Persistent Organic Pollutants (POPs), Department of the Health Institute in Ostrava, carried out analyses of the presence of phthalates in **water and dust in 2006** (Chapter 10). Analytical determination of all the targeted analytes was carried out by combination of gas chromatography and mass spectrometry (HRGC/MS).

Health Institute in Ústí nad Labem carried out analyses of phthalates in **indoor dust in 2008** (chapter 10), using the same analytical method as the Health Institute in Ostrava for the previous dust sample analyses in 2006.

4. Medical Equipment (2012)

In 2012, Arnika ordered analyses of five pieces of medical equipment, commonly used in healthcare. Five randomly chosen samples of plastic tubes made of plasticized PVC (see Table 2 below), bought through e-shops, were subjected to the analyses. A certified laboratory analysed phthalate contents in the products, namely diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), and di(2-etylhexyl) phthalate (DEHP). Except DEHP, all the phthalates mentioned above were below the limit of quantification. DEHP was found in four of the five samples, in amounts higher than 20 % by weight (wt. %) in all these four samples. Because DEHP was the only phthalate exceeding the limit of measurement in the samples, the total phthalate contents in the table corresponds also to the DEHP contents in the samples (see Table 2). Pictures of samples can be seen in the Annex 13.2.

Table 2: Tested samples of tubes used in healthcare. The phthalate content lower than 0.1 wt. % in the product may be caused unintentionally, it may be an impurity in the raw material.

Sample name	Producer	Sample details	Sum of phthalates (wt. %)
Heidelberg extension tube	B. BRAUN MEDICAL (Melsungen, Germany)	Extension tube for infusion and transfusion sets	28.78
Universal tube GAMAPLUS	GAMA Group a.s. (Jimramov, Czech Republic)	Transparent PVC tube, 1.9/2.9 mm, length 450 mm, end Female Luer Lock/Male Luer	26.70
Extension tube KD-LINE	KD Medical (Berlín, Germany)	Extension tube for connecting transfusion or infusion sets to further components	22.41
Connecting infusion tube CHIRALINE	CHIRANA T.INJECTA A.S. (Stará Turá, Slovakia)	Extension tube for connecting infusion or transfusion sets to further components	21.98
Compat GO Set Portable	NESTLE Nutrition (Frankfurt, Germany)	Nutrition set for application of enteral nutrition, for single use	0.016

DEHP is a hazardous substance disrupting the human endocrine system. This substance is released from the medical equipment and enters blood or artificial nutrition, flowing through the tubes into patients' bodies. In the case of products in e-shops, data on phthalate contents were not available. In that time, these data had to be present on the product packaging only, according to the legislative requirements. Complete ban of use of this phthalate has been valid since 2015, however, this ban does not apply to medical equipment, in view of limitations of effectiveness of the REACH Regulation (EC No. 1907/2006) (European Parliament and Council 2006). Nevertheless, DEHP had to be replaced in a number of other products already, what is obvious also from analyses of other products made of PVC in the subsequent chapters. DEHP is still produced, for example, by the Czech chemical plant DEZA Valašské Meziříčí from the group Agrofert.[2]

Fig.1: Commonly used plastic tubes during medical care of a newborn. Photo: Topato, wikimedia.org, licence cc-by-2.0.

[2] This industrial company published a statement on its website, stating that „**DEZA, a. s. wants to continue DEHP manufacture and selling, as long as:**
- The European legislation enables its manufacturing, transport, and use.
- The current and future customers will want to use DEHP.
- The manufacture and selling will be economically meaningful."
DEZA. (2013). "Ftalanhydrid, změkčovadla a estery. (Phthalic anhydride, plasticizers and esters)." Retrieved 10/10/2020, 2020, from http://www.deza.cz/ftalanhydrid-zmekcovadla-a-estery.

5. Childcare Articles (2012)

In 2012, also childcare articles were analysed, specifically nasal aspirators and diaper changing pads. The articles were selected in the way to cover the whole price spectrum, and also products often designated phthalate-free by the producers. The parts of the articles that come into direct contact with the newborn body were tested. In total, 5 nasal aspirators, and 6 diaper changing pads were analysed. The results are presented in Tables 3 and 4. In the both tables, products are arranged according to the purchase price, from the cheapest to the most expensive one. Photos of analyzed articles are shown in the Annex 13.3.

Table 3: Results of analyses determining phthalate presence in nasal aspirators for infants, from the cheapest to the most expensive product. Products with higher values than permitted by the legislation valid in the time of the analysis are marked in bold.

Sample and tested part	Producer/ Distributor	DINP wt. %	DIDP wt. %	DNOP wt. %	BBP wt. %	DBP wt. %	DEHP wt. %
GAMA - nasal aspirator for infants - transparent tube	GAMA GROUP, a.s., Czech Republic	<0.005	<0.005	<0.001	<0.001	<0.001	0.021
GAMA - nasal aspirator for infants - mouthpiece	**GAMA GROUP, a.s., Czech Republic**	**<0.005**	**<0.005**	**<0.001**	**<0.001**	**<0.001**	**0.792**
OTRIVIN - nasal aspirator - transparent tube	Novartis Consumer Health S.A., Spain	<0.005	<0.005	<0.001	<0.001	<0.001	<0.001
FARLIN - nasal aspirator with one-way valve - transparent tube	Made in Taiwan/ Farlin CZ, Czech Republic	<0.005	<0.005	<0.001	<0.001	<0.001	<0.001
NOSÁTKO - nasal aspirator (plastic set connectable to a vacuum cleaner) - transparent tube	**Ranyák György üvegtechnikus, Hungary/ CEUMED s.r.o., Czech Republic**	**<0.005**	**<0.005**	**<0.001**	**<0.001**	**0.003**	**20.15**
ARIANA BABY-VAC, Ergonomic 2 (nasal aspirator connectable to a vacuum cleaner) - transparent tube	Illés Csók és Társa, Hungary/ Morchella s.r.o, Czech Republic	<0.005	<0.005	<0.001	<0.001	<0.001	0.013

From the total amount of the tested aspirators, two exceeded the limit, and in two of them the amounts were below the limit of quantification (see Table 3). One of the products, designated NOSÁTKO, contained an alarming amount of the tested phthalates - 20 % by weight. On the contrary, in the case of diaper changing pads for infants, only one of the products exceeded the limit, and in three of them the values could not be determined due to the fact that the amounts were below the limit of quantification of the used analytical method, as shown in Table 4.

The overall results of the 2012 analyses could be regarded satisfactory. However, it is alarming that phthalates were found even in products declared phthalate free by their manufacturers.

Of the 11 products, 3 exceeded the permitted concentration of 0.1 wt. % of the product. The phthalate content lower than 0.1 wt. % in the product may be caused unintentionally, for example, it may be an impurity in the raw material.

Table 4: Results of analyses determining phthalate presence in diaper changing pads, from the cheapest to the most expensive product. The product with higher value than permitted by the legislation valid in the time of the analysis is marked in bold.

Sample name	Producer/ Distributor	Sample details	DINP wt. %	DIDP wt. %	DNOP wt. %	BBP wt. %	DBP wt. %	DEHP wt. %
Diaper changing pad Akuku	Albls, Poland/ CARERO s.r.o., Czech Republic	Manufactured of two layers of PEVA foil	<0.005	<0.005	<0.001	<0.001	<0.001	<0.001
Soft diaper changing pad on a chest of drawers Méďa	/Zdizslaw Krajewski - Scarlett, Czech Republic	Covered by a PVC foil with printing by food colouring, phthalate free	<0.005	<0.005	<0.001	<0.001	<0.001	<0.001
Diaper changing pad Jesica 2012	CEBA Sp., Poland/ Babypoint, Czech Republic	100 % phthalate free PVC	<0.005	<0.005	<0.001	<0.001	<0.001	0.002
Diaper changing pad Fisher-Price	Fisher-Price (Mattel), United Kingdom/ Dampex, Czech Republic		<0.005	<0.005	<0.001	<0.001	<0.001	<0.001
Diaper changing pad A3+ Polly	**CEBA Sp., Poland/ Babypoint, Czech Republic**	**100 % phthalate free PVC**	**1.57**	**<0.005**	**<0.001**	**<0.001**	**<0.001**	**0.076**
Diaper changing pad with cover Paris - Candide	Candide, France/ VITPEA, Czech Republic	100 % phthalate free PVC, filling 100 % polyurethane foam	<0.005	<0.005	<0.001	<0.001	<0.001	0.005

6. Children Footwear (2016)

In 2016, Arnika focused on phthalates and heavy metals in children footwear. In total, eight samples of summer shoes (7 for children and 1 for women) were bought in various brick and mortar stores on the territory of the Czech Republic. According to the information on the product packaging, all the bought footwear was manufactured in China.

In the first testing phase, all the bought samples were screened using the hand-held X-ray spectrometer NITON XL3t 800 (Thermo Fisher Scientific, USA), to test presence of PVC and heavy metals. In 3 samples of children summer shoes, the screening by the hand-held spectrometer identified high lead contents. Subsequently, these samples were analysed for lead content by an accredited laboratory. Further, in one sample, a test of Pb leachability was carried out, in an alkaline and acid leachate (Válek 2016).

Parts of the bought shoes made of PVC were sent for analyses for determination of phthalate contents. The contents of the following phthalates were measured: diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), di(2-etylhexyl) phthalate (DEHP), and dipentyl phthalate (DPP) (Válek 2016). Although the tested phthalates were regulated by a number of regulations in the EU in the time of the analyses, total amounts of phthalates in children footwear was not regulated by the legislation.[3] Regulation (EC) 1907/2006 REACH lays down only that the total amount of DEHP, DBP, and BBP, must not exceed 0.1 % by weight in any toys and childcare articles. Phthalates DINP, DIDP, and DNOP, had not exceed 0.1 % by weight in toys and childcare articles which could be placed in the mouth by children. Since 2007, these restrictions were not limited by the age of children for which the products were intended (Válek 2016).

A detailed description of the tested products is given in Tables 5, 6, and 7.

Results of Phthalate Content Analyses

Results of analyses determining contents of the tested phthalic acid esters are given in Table 5. The contents are stated in percent by weigh (wt. %), the measurement error was up to 10 %. The table includes only the phthalates that exceeded the limit of detection of the used method, being 0.05 wt. %, namely DBP and DEHP. Because also other phthalic acid esters (diisobutyl phthalate, DIBP), and even one citrate (tributyl citrate, TBC), were found in the samples, Table 5 states also the determined contents of these substances. The results prove that presence of plasticizers based on phthalic acid esters was not found only in sample No. 5 - slippers for boys. In this sample, tributyl citrate (TBC) was used as the plasticizer instead.

[3] With a new regulation, entry 51 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals within the framework of the European chemical policy has been changed as of July 2020, expanding restrictions of phthalates DEHP, DBP, BBP, and DIBP, to all plastic products. European Commission (2018). Commission Regulation (EU) 2018/2005 of 17 December 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) (Text with EEA relevance.). Official Journal of the European Union: L 322/314-319. For more information, please see Chapter 10.

Table 5: Contents of plasticizers in samples of summer shoes (wt. %).

Sample No.	Tested part	DIBP*	DBP	DEHP	TBC+
1	Decorations: flowers and teddy bear	-	-	44.5	-
2	Decorations: beetles	-	-	43.5	-
3	Artificial leather under heal	-	4.7	13.7	-
4	Belt over instep	37.3	-	-	-
5	Belt over instep	-	-	-	35.8
6	Belt over instep	8.2	25.3	12.8	-
7	Belt over instep	16.7	9.5	19.0	-

[-] < 0.05 wt. %.

* in relation to response factor of DBP, + in relation to response factor of DEHA

The most often present phthalate was DEHP. High DEHP amounts were found in 5 of the 7 tested samples, in the range 12.8 – 44.5 wt. %. In samples Nos. 1 and 2, DEHP formed almost a half of the total weight of the tested parts; in the both cases, these parts were colourful decorations on the outer sides of the slide sandals.

Significant contents of phthalates DIBP and DBP were found in 3 of the 7 tested samples. In sample No. 4, slide sandals for girls, only the phtalete DIBP was found in the belt over instep with a content being almost 40 wt. %.

In samples Nos. 6 and 7, high contents of three phthalates (DIBP, DBP, and DEHP) were found in the belts over instep. Their total contents were almost 47 and 46 wt. %, respectively (Válek 2016).

Results of Lead (Pb) Content Analyses

In the selected samples 1, 3, and 8, lead (Pb) contents were in the range 170.5 – 9,923.6 mg/kg of dry matter (Table 6). In sample No. 8, the amount of almost 10 g/kg, corresponding to 1 wt. %, was found in the dark, i.e., more coloured, part of the inner artificial leather.

On the basis of the previous analysis results, also tests of Pb leachability from the light and dark parts of the sole made of artificial leather were carried out, in accordance with the standard given in Decree No. 84/2001 Coll. (MZD 2001). According to the standard, limit for Pb leaching from this kind of products is 0.2 mg/kg. As follows from Table 7, amounts of leached Pb were in the range 10.8 – 14. 8 mg/kg of the leachate. The leachability limit, being 0.2 mg/kg of the leachate according to the Decree, was exceeded in all the four cases, 73.5-times and 54-times, respectively, in the case of acid and alkaline leachates of the light part of the artificial leather, and 70-times and 74-times, respectively, in the case of acid and alkaline leachates of the dark part of the artificial leather (Válek 2016).

Table 6: Pb contents in selected samples of children footwear.

Sample No.	Tested part	Pb (mg/kg dry matter)
1	Decoration - teddy bear	170.5
3	Decoration - petals	6272.2
8	Inner light artificial leather	4936.3
8	Inner dark artificial leather	9923.6

Table 7: Pb contents in leachates of artificial leather in children footwear.

Sample No.	Tested part	Sweat modelling solution	Pb (mg/kg)
8	Light artificial leather	Acid	14.7
8	Light artificial leather	Alkaline	10.8
8	Dark artificial leather	Acid	14.0
8	Dark artificial leather	Alkaline	14.8

Fig. 2: In 2007, Arnika started analysing phthalates in toys made of plasticized PVC. The photo depicts the head of the then project, Mgr. Miroslava Jopková, with the analysed samples. Photo: Jindřich Petrlík.

7. Toys

Young children, together with pregnant women, form the group that is most endangered by impacts of chemical substances, including phthalates. Toxic substances, affecting developing organisms of children, may cause serious damage to health, this being true also for children in wombs of their mothers. Phthalates rank among such substances. Their impacts on human health, including health and development of children, are briefly described in Chapter 2.1.

Because of that, Arnika monitors, in the long term, their contents in toys, but also in other products children come into contact with, such as childcare articles, equipment of children's rooms, and clothing for children. In addition to focus on the Czech market, Arnika prepared also an extensive study of products for children in Belarus (Petrlík, Straková et al. 2014). Its results are briefly summarised in Annex 13.1.

7.1 Toys and Toy Packaging on the Czech Market (2007)

In 2007, Arnika published results of its first investigation of phthalates in toys on the Czech market (Jopková, Kleger et al. 2007). In addition to phthalates, it ordered also analysis of 4-nonylphenol presence in articles made of plasticized PVC. Because phthalates were expressly banned in toys for children under the age of three years, our attention focused, in particular, on functional closable toy packaging made of PVC, that could, with a high likeliness, stay in the reach of children together with the toy, not manufactured of PVC as such. Further, chemical composition was analysed of toys made of PVC, declared not to be suitable for children under three years of age because of presence of small parts. However, toys of this kind often seem intended for younger children, due to their nature (squeak toys, inflatable animals). Photos of the samples, with description of the places of their purchase, may be found in Annex 13.4.

In 2007, when the study was carried out, six most widely used phthalates (DEHP, DBP, BBP, DINP, DIDP, and DNOP) were banned by the legislation in toys for children under the age of three years only. However, a new EU directive came into force in the same year, tightening the then regulations by the requirement to ban the six phthalates in all products for children which could be placed in the mouth by children (thus, not only in toys for children under the age of three years) (Jopková, Kleger et al. 2007). Because of that, a further purpose of the study was to find out whether the market was prepared for coming of the new EU directive into force.

In total, five samples of toys and their packaging were tested. In all the cases, the material was plasticized PVC. Summary results of analyses for phthalate contents, carried out by the laboratory ITC Zlín, are given in Table 8. Of the five tested samples, presence of phthalic acid esters was found in three cases, in the range from 26.12 wt. % to 43.54 wt. % of the products (samples Nos. 1, 3, and 5). The laboratory succeeded in exact identification of the used phthalates in the case of sample No. 5 (inflatable toy) only, namely a mixture of DEHP (di(2-etylhexyl) phthalate), and DINP (diisononyl phthalate). In the case of samples 1 and 3, the laboratory could not identify the used phthalates exactly, because it did not have the corresponding standards for confirmation.

In the other products, the amounts of phthalic acid esters did not exceed the limit of detection, 0.1 wt. %, for the mixture of DBP (dibutyl phthalate), BBP (benzyl butyl phthalate), DEHP (di(2-etylhexyl) phthalate), DNOP (di-n-octyl phthalate), DINP (diisononyl phthalate), and DIDP (diisodecyl phthalate). In these cases, substances based on citrates (tributyl citrate – TBC), and adipates (diisononyl adipate) were used as the plasticizers.

In four toy samples, also presence of 4-nonylphenol was analysed. This substance was found in three of them, in the amounts from 0.13 to 4.41 mg/kg. In sample No. 2, concentration of 4-nonylphenol did not exceed the limit of detection, 0.1 mg/kg (Jopková, Kleger et al. 2007).

Table 8: Contents of phthalic acid esters (plasticizers) in toy samples (wt. %) (Jopková, Kleger et al. 2007).

Sample	Sum of plasticizers	Type of plasticizer (phthalate)
1: PVC packaging for blocks	26.12	Higher phthalic acid ester, probably with molecular weight of 418
2: Turtle toy	36.95	Tributyl acetyl citrate, di-isononyl adipate
3: Inflatable ball plug	43.54	Higher phthalic acid ester, probably with molecular weight of 418
4: PVC packaging for a toy „book“	27.57	di-isonyl adipate
5: Inflatable toy	30.01	mainly mixture of DEHP and DINP

To summarize, high contents of phthalic acid esters were found in three products, and, because of that, a high risk existed that children coming into contact with the products would be subjected to an increased exposure to these substances. In spite of a considerable shift towards higher safety in relation with use of phthalic acid esters in children's toys, achieved by adoption of corresponding legislative measures, children were subjected to a higher exposure to these substances in the time when the analyses were carried out, namely in 2007. This concerned, in particular, toys declared not to be suitable for children under three years of age. Because of this declaration, the relevant regulations did not apply to them. A similar situation was found also in the case of toy packaging made of PVC (Jopková, Kleger et al. 2007).

7.2 Loom Band Charms and Scoubidou Strings (2014)

In 2014, Arnika ordered tests of loom bands, loom band charms, and also scoubidou strings Wiky, very popular among children at that time. The analyses were carried out as a reaction to analyses performed in the United Kingdom and Ireland, where phthalate contents reached up to 50 wt. % of the products in certain loom band sets, i.e., they exceeded the amount permitted by the EU regulation 500-times (Petrlik, Petrlikova et al. 2014).

Table 9: Results of DEHP and DOIP analyses of loom band charms and strings in 2014. On the basis of Arnika's order, the analyses were carried out by the Central Laboratory of the University of Chemistry and Technology in Prague.

Sample	Material	DEHP (wt. %)	DOIP (wt. %)
1a: Charm (peace)	PVC	6.4	25.1
2a: 2 to 3 charms (panda)	PVC	2.9	36.3
3a: 2 to 3 charms (star, moustache)	PVC	41.9	-
4a: Charms (cat, flower)	PVC	22.2	14.4
5a: Charms (butterfly, cake)	PVC	-	28.0
6a: Mix of strings	Non PVC	-	-
7a: Mix of strings	Non PVC	-	-
8a: Mix of strings	Non PVC	-	-
9a: Mix of strings, same colour and material	Non PVC	-	-
10a: Mix of strings	Non PVC	-	-
11a: Charms (smile, bee)	PVC	41.5	-
1b: Wiki scoubidou strings	PVC	8.3	15.9

[-] < 0.05 wt. %.

The analyses ordered by Arnika did not find hazardous phthalates in loom bands themselves, however, presence of phthalate DEHP was proved in five of the eleven tested samples of loom band charms, in the amounts from 2.9 wt. % to 41.9 wt. %. The further tested phthalate was DOIP. It was found in four charms, in the amounts from 14.5 wt. % to 36.3 wt. %. The both phthalates were present in three of the eleven charms. The last tested product were Wiki scoubidou strings (sample 1b). They contained the both hazardous phthalates, 8.3 wt. % of DEHP, and 15.9 wt. % of DOIP. As may be seen in Table 9, all the positive products were made of PVC. Exemplary photos of the charms and Wiki scoubidou strings may be found in Annex 13.5. In contrast to scoubidou strings and loom band charms, the loom band themselves were not found to be made of PVC in none of the tested loom band sets (Petrlikova and Brabcova 2014).

8. School Supplies (2008 – 2014)

Arnika focused on school supplies three times, namely in 2008, 2010, and 2014. In 2008, an analysis was carried out, testing, in total, 9 samples of randomly bought school supplies. The samples were analysed for total contents of plasticizers, and, further, for presence of phthalates DEHP, and DINP.

As may be seen in Table 10, the analysis proved phthalate presence in all the samples. DEHP presence was found in eight of the nine samples, in the amounts between 8.97 and 37.14 wt. %. The highest amount of this phthalate was present in sample No. 4, eraser in the lemon shape. Phthalate DINP was found in four samples, in the amounts between 1.34 and 17.62 wt. %. The highest DINP amount was present in sample No. 1, pencil sharpener having the shape of a bunny. From Table 10, it is obvious that the remaining amounts to the total wt. % of plasticizers in the samples were formed by other plasticizers, that, however, were not tested that time.

Table 10: Contents of phthalic acid esters (plasticizers) and the individual phthalates in samples of school supplies in 2008 (wt. %). The analyses were carried out by the laboratory of the Institute for Testing and Certification in Zlín.

Sample	Content of extractable substances (softeners)	DEHP	DINP
1: Pencil sharpener „bunny“	37.94	-	17.62
2: Wrapping for „pupil's index“	21.85	16.34	-
3: Casing for wood crayons	29.46	17.32	1.34
4: Lemon-like eraser	50.12	37.14	-
5: Top foil from alphabet folder	20.12	12.39	-
6: Inner foil from alphabet folder	21.22	11.41	-
7: Pencil case „handbag“ (transparent)	24.56	12.08	1.96
8: Pencil case with flowers	17.68	10.87	-
9: Pencil case - transparent	23.12	8.97	3.3

In 2010, in total nine samples of school supplies made of PVC were tested, bought in Prague, Ostrava, České Budějovice, and Děčín. Again, the samples were analysed for contents of phthalic acid esters, however, the spectrum of the specifically analysed phthalates was much wider this time than in 2008. Thus, we know concentrations of the following substances in the school supplies: DINP, DIDP, DNOP, BBP, DBP, and DEHP. Table 11 shows the list of samples and amounts of the individual phthalates exceeding 0.1 wt. %, in % by weight. The phthalate content lower than 0.1 wt. % in the product may be caused unintentionally, it may be an impurity in the raw material.

As follows from the results, five of the nine tested products contained some of the six tested phthalic acid esters, in the amounts from 12.67 wt. % up to 18.18 wt. %. The most often present phthalate was DEHP, found in four samples (Nos. 1, 5, 6, and 7), and, further, DINP was found in sample No. 2.

Table 11: Contents of the individual phthalates in the samples of school supplies in 2010 (wt. %). The analysis was made by the Institute for Testing and Certification in Zlín.

Sample	DINP	DIDP	DNOP	BBP	DBP	DEHP
1: Pencil case „Sweet cat" – upper coating	-	-	-	-	-	17.02
2: Pencil case „Polly" – upper coating	16.15	-	-	-	-	-
3: Set of markers „Double marker" – packaging	-	-	-	-	-	-
4: Pencil case „blue transparent"	-	-	-	-	-	-
5: Set of 6 fibre tip pens TESCO – packaging	-	-	-	-	-	12.67
6: Transparent cover for exercise book with music paper	-	-	-	-	-	15.50
7: Exercise book cover (transparent A5)	-	-	-	-	-	18.18
8: Eraser – rubber „triangle"	-	-	-	-	-	-
9: Eraser	-	-	-	-	-	-

[-] < 0.1 wt. %.

Arnika continued testing of samples of school supplies made of PVC, bought in the Czech Republic, in 2014. Eleven samples were tested for DINP, DIDP, DNOP, BBP, DBP, and DEHP, similarly as in 2010. Table 12 shows the list of samples and amounts of the individual phthalates exceeding 0.1 wt. %, in % by weight.

As follows from the results, three of the eleven tested products contained some of the six analysed phthalates, in the amounts from 0.28 wt. % up to 23.1 wt. %. Again, the most often present phthalate was DEHP, found in three samples (Nos. 1, 2, and 3), further, DINP was found in two samples (Nos. 2 and 3), and DBP in one sample (No. 1). As may be seen, sample No. 1, pencil case „21st century" – surface part, contained three of the six analysed phthalic acid esters.

Table 12: Contents of the individual phthalates in the samples of school supplies in 2014 (wt. %).

Sample	DINP	DIDP	DNOP	BBP	DBP	DEHP
1: Pencil case „21st century" – surface part	23.1	-	-	-	0.28	3.51
2: Pencil case „Transformers" – surface part	-	-	-	-	-	15.49
3: Clear foil on a notebook from the pencil case „Transformers"	3.74	-	-	-	-	16.56
4: Coloured pencils from the pencil case „Transformers" – coating foil	-	-	-	-	-	-
5: Coloured rubber eraser „Milan"	-	-	-	-	-	-
6: Clear pencil case Tesco	-	-	-	-	-	-
7: Diving glasses Tecno pro – clear plastic in contact with face	-	-	-	-	-	-
8: Diving glasses Tesco – clear plastic in contact with face	-	-	-	-	-	-
9: Pencil case „Turtles" – surface part	-	-	-	-	-	-
10: Black rubber eraser from the pencil case „Transformers"	-	-	-	-	-	-
11: Purple rubber eraser from the pencil case „Transformers"	-	-	-	-	-	-

[-] < 0,1 hm. %.

In spite of the fact that results of school supply testing in 2010 were better than in 2008, DEHP was still proved in a third of the tested products, and DINP and DIDP in a sixth part of the products. In all the cases, the amounts were alarming. However, even this was an improvement in comparison with 2008, when DEHP and/or DINP were found in all the nine tested samples. In 2014, some of the six phthalic acid esters was detected in less than a quarter of the samples, however, the amounts there were high again. This can be still regarded as an improvement, however, it is obvious that market control continues to be necessary. Moreover, it has to be noted that we did not test the presence of phthalate DOIP in the products. This substance could be present, as follows, for example, from analyses of samples from Belarus, and analyses of popular loom band charms (see Annex 13.1, and Chapter 7.2).

9. Wallpapers and Floor Coverings (2010)

In 2010, Arnika ordered analyses of wallpapers suitable for children's rooms, due to their picture designs. As follows from Table 13, all the three tested wallpapers contained considerable amounts of at least one of the six analysed phthalic acid esters. Samples 1 and 2 contained 13.15 and 13.48 wt. %, respectively, of DIDP, and sample 3 contained 12.17 wt. % of DINP. Photos of tested wallpapers are shown in Annex 13.6.1.

Table 13: Contents of the individual phthalates in samples of wallpapers in 2010 (wt. %). Source: (Petrlík and Kristian 2012).

Sample	DINP	DIDP	DNOP	BBP	DBP	DEHP
1: Adhesive foil "Mickey Mouse, Dumbo, Donald Duck"	<0.005	**13.15**	<0.001	<0.001	<0.001	<0.001
2: Adhesive foil "Winnie the Pooh"	<0.005	**13.48**	<0.001	<0.001	<0.001	<0.001
3: Wallpaper "with parrots"	**12.17**	<0.005	<0.001	<0.001	<0.001	<0.001

In 2011, Arnika focused on floor coverings made of plasticized PVC, and ordered their analyses for the presence of six hazardous phthalates. As follows from Table 14, toxic phthalates were present in the five tested samples in the amounts from 0.11 to 17.03 wt. % of the product. Phthalate DINP was present in all the samples, and DEHP was found in significant amounts in two samples (Nos. 4 and 5). Detailed information on origin of the individual samples of floor coverings is given in Annex 13.6.2.

Table 14: Contents of the individual phthalates in samples of floor coverings in 2011 (wt. %). Source: (Petrlík and Kristian 2012).

Sample	DINP	DIDP	DNOP	BBP	DBP	DEHP
1: Floor covering Polo	8.33	<0.005	<0.001	<0.001	0.002	0.12
2: Floor covering Sawa Step	17.03	<0.005	<0.001	<0.001	<0.001	<0.001
3: Floor covering Rodos	14.31	<0.005	<0.001	<0.001	0.002	<0.001
4: Floor covering Flexar	0.49	<0.005	<0.001	<0.001	<0.001	9.36
5: Floor covering d-c-fix	0.11	<0.005	<0.001	<0.001	0.10	4.64

Fig. 3: Dust sampling was carried out using a device that had been tested whether sample contamination had not taken place during the sampling. After each sampling, the device was cleaned thoroughly. Photo: Ondřej Petrlík.

10. Phthalates in Indoor Dust and Rainwater (2006 and 2008)

Most often, amounts of phthalates in indoor environment are monitored in dust samples. Because of that, Arnika carried out its first series of analyses of indoor dust, but also of rainwater, in 2006. The samples were taken in four places in the Czech Republic, in three cities: in Prague, Ústí nad Labem, and Ostrava, and also at Churáňov, where a meteorological observatory is located, but it is a place high in the mountains in the Protected Landscape Area Blanský Les. Characterization of the places of sampling is given in Tables 15 and 17. Dust and water samples were analysed for presence of fifteen phthalates, listed in Tables 16 and 18. The research itself was described in detail in a study published in 2006 (Watson 2006). Chemical analyses for the study were carried out by the laboratory of the Health Institute in Ostrava.

Table 15: List of samples with places of sampling. Source: (Watson 2006)

Sample No.	Sampling place
4250	Prague - Prague office of Dr. Martin Bursík, Sněmovní 7, chairman of the Green Party
4251	Ústí nad Labem - office of the governor of the Ústecký Region, Ing. Jiří Šulc
4252	Churáňov, Hydrometeorological observatory of CHMI, at the top of the mountain Churáňov
4253	Ostrava - building of the Regional Authority of the Moravian-Silesian Region

In dust from indoor areas, phthalates DBP and DEHP were found in the highest amounts, in the order of hundreds µg/g. The highest concentrations of phthalates were detected in dust samples from the Regional Authority building in Ostrava (2103 µg/g), and, paradoxically, even higher ones in dust from the observatory at Churáňov (2912 µg/g). The lowest amount of phthalates was present in the sample from the Prague office of Martin Bursík.

Table 16: Results of analyses of phthalate concentrations in dust samples in 2006. Source: (Watson 2006), adapted

Sample	Abbreviation	4250	4251	4252	4253
Place		Prague	Ústí n. Lab.	Churáňov	Ostrava
Unit		µg/g	µg/g	µg/g	µg/g
Dimethyl phthalate	DMP	< 1.6	< 3.4	< 2.3	< 1.6
Diethyl phthalate	DEP	< 2.0	22	4.0	8.6
Diisobutyl phthalate	DIBP	4.7	42	44	77
Dibutyl phthalate	DBP	20	84	460	93
Bis(2-methoxyethyl) phthalate	DMEP	< 34	< 68	< 42	< 32
Bis(4-methyl-2pentyl) phthalate		< 2.7	< 5.4	< 3.4	< 2.6
Bis(ethoxyethyl) phthalate		< 35	< 64	< 30	< 26
Dipentyl phthalate	DPP	< 1.8	< 3.3	< 1.5	< 1.3
Dihexyl phthalate	DHXP	< 2.2	< 3.9	< 1.9	< 1.6

Benzyl butyl phthalate	BBP	< 2.6	< 11	< 5.6	20
Bis(2-butoxyethyl) phthalate	BEP	< 10	< 41	< 22	< 18
Dicyclohexyl phthalate	DCHP	10	< 6.9	< 3.6	< 3.0
Di(2-ethylhexyl) phthalate	DEHP	10	810	2400	1900
Di-n-octyl phthalate	DNOP	< 3.2	5.8	3.5	4.7
Diisononyl phthalate	DINP	< 4.0	< 7.3	< 3.4	< 3.4
Sum of phthalates		45	964	2912	2103

As for rainwater, phthalates were found in all the four taken samples, in the following order from the highest to the lowest phthalate content: Ostrava, Churáňov, Prague, and Ústí nad Labem. Not only DBP and DEHP, but also phthalates DEP and DIBP were detected in the order of hundreds to thousands of ng/L. For more information, please see Table 18.

Table 17: List of samples with places of sampling. Source (Watson 2006)

Sample No.	Sampling place
4144	Ostrava, Ferona building (one of the highest buildings in the city)
4254	Prague 3, Chlumova 17 (Arnika office building)
4255	Ústí nad Labem, Elementary School in Eli ky Krásnohorské Street 310/76
4256	Churáňov, Hydrometeorological observatory of CHMI, at the top of the mountain Churáňov

Table 18: Results of analyses of phthalate concentrations in water samples in 2006. Source: (Watson 2006), adapted

Sample	Abbreviation	4144	4254	4255	4256
Place		Ostrava	Prague	Ústí n. Lab.	Churáňov
Unit		ng/L	ng/L	ng/L	ng/L
Dimethyl phthalate	DMP	< 8.8	10	8.4	7.7
Diethyl phthalate	DEP	620	290	240	320
Diisobutyl phthalate	DIBP	1500	510	290	570
Dibutyl phthalate	DBP	3600	1500	810	2600
Bis(2-methoxyethyl) phthalate	DMEP	< 169	< 132	< 140	< 157
Bis(4-methyl-2pentyl) phthalate		16	< 10	< 11	< 12
Bis(ethoxyethyl) phthalate		< 130	< 88	< 120	< 130
Dipentyl phthalate	DPP	< 6.6	< 4.5	< 6.2	< 6.4
Dihexyl phthalate	DHXP	< 7.9	< 5.4	< 7.4	< 7.7
Benzyl butyl phthalate	BBP	< 25	< 16	< 19	< 24
Bis(2-butyoxytehyl) phthalate	BEP	< 95	< 62	< 74	< 91
Dicyclohexyl phthalate	DCHP	< 16	96	< 12	< 15
Di(2-ethylhexyl) phthalate	DEHP	1100	640	600	1100
Di-n-octyl phthalate	DNOP	< 8.3	< 6.0	< 7.9	< 9.0

Diisononyl phthalate	DINP	< 10	< 7.4	< 9.8	< 11
Sum of phthalates		6836	3046	1948	4598

Two years later, in 2008, Arnika continued its analyses of phthalates in dust samples. The dust samples were taken in various residential and public buildings in the Pardubický and Vysočina Regions, and in the capital city of Prague. Dust samples for phthalate analyses were taken, in total, in ten rooms. The sampling places were rooms in flats, offices, but also, for example, in elementary schools (Petrlík and Kristian 2012). A detailed description of the rooms, including their fixtures and fittings, is given in Table 19. The analyses were carried out by the laboratory of the Health Institute in Ústí nad Labem.

Table 19: List of buildings, rooms, and their fixtures and fittings.

Sample	Place of testing	Sample details and fixtures and fittings of the sampling place
VYS 1	Flat without PVC	Floor made of wood + tiles, wooden windows, chipboard furniture
VYS 2	Building of the Regional Authority of the Vysočina Region	Offices - secretariat of the Governor, Department of External Relations; floors: carpet, wooden windows, chipboard furniture, plastic upholstered chairs
VYS 3	Kindergarten	Kindergarten (one of three parts) 20 children from 3 to 6 years; floors: carpet + PVC, wooden windows, wooden and chipboard furniture, some toys made of PVC
VYS 4	Dental office	Dental office; floor – probably PVC, plastic windows, 5 armchairs made of artificial leather (PVC) and dental chair with dental engine, chipboard furniture, many cables to equipment
VYS 5	Flat with PVC	Floors: PVC + carpet, plastic windows, wooden and chipboard furniture
VYS 6	Flat with PVC	Childless couple; newly reconstructed house - floors made of PVC in the whole flat, PVC windows, chipboard furniture, kitchen - chairs and benches with artificial leather, PVC tablecloth
PAR 1	Elementary school – dining room with PVC	Dining room; floor: PVC
PAR 2	Elementary school – staff room	Staff room; floor: linoleum
PRA 1	Flat with PVC	Kitchen; floor: PVC
PRA 2	Ministry of Education, Youth, and Sport of the Czech Republic	Ministry of Education, office of the Minister, Ondřej Liška; floor: parquets and tiles

In total ten dust samples were analysed for presence of fifteen phthalates, namely dimethyl phthalate (DMP), diethyl phthalate (DEP), diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), bis(2-methoxyethyl) phthalate (DMEP), bis(4-methyl-2-pentyl) phthalate, bis(ethoxyethyl) phthalate, dipentyl phthalate (DPP), dihexyl phthalate (DHXP), benzyl butyl phthalate (BBP), bis(2-butoxyethyl) phthalate (BEP), di(2-etylhexyl) phthalate (DEHP), dicyclohexyl phthalate (DCHP), di-n-octyl phthalate (DNOP), and dinonyl phthalate (DNP). The results are summarised in Table 20, listing concentrations of the phthalates present in amounts over 1 µg/g in at least one of the samples.

Table 20: Results of analyses of dust from various rooms carried out in 2008, in µg/g (only results over the limit of detection of the used method are included) (Petrlík and Kristian 2012), adapted.

Sample – Place of testing	PVC	DHP	DIBP	DBP	BBP	DEHP	Sum
Unit		µg/g	µg/g	µg/g	µg/g	µg/g	µg/g
VYS 1: Flat without PVC	NO	<1	49	131	<1	210	390.0
VYS 2: Building of the Regional Authority of the Vysočina Region	NO	<1	30	24	<1	131	185.0
VYS 3: Kindergarten	YES	12	14	187	2.3	969	1184.3
VYS 4: Dental office	YES	<1	8.5	156	<1	2165	2329.5
VYS 5: Flat with PVC	YES	6.9	6.8	74	<1	1429	1516.7
VYS 6: Flat with PVC	YES	<1	4.6	18	<1	193	215.6
PAR 1: Elementary school – dining room with PVC	YES	<1	30	38	<1	2813	2881.0
PAR 2: Elementary school – staff room	NO	2.7	61	30	<1	397	490.7
PRA 1: Flat with PVC	YES	15	45	40	4.9	208	312.9
PRA 2: Office of the Minister of Education	NO	<1	66	186	9.4	254	515.4

Table 21 provides comparison of results of dust analyses obtained in 2006 and in 2008. Phthalate concentration found in the dining room with floor covering made of PVC in Pardubice is comparable with the one detected in dust from the meteorological observatory at Churáňov, and concentration in the dental office, also with floor covering made of PVC, is similar to the one detected in the Regional Authority building in Ostrava. With only minor exceptions, rooms with floor coverings made of plasticized PVC show much higher phthalate concentrations than the ones without PVC, even if they are located in the same building (see elementary school – dining room and staff room in Pardubice). Just because of PVC as a source of increased phthalate concentrations, Swedish researchers regarded this type of floor covering as the cause of increased occurrence of asthma in children (Larsson, Hägerhed-Engman et al. 2010), after they proved relation between higher phthalate concentrations and presence of plasticized PVC in rooms, either in floor coverings or in wallpaper (Bornehag, Lundgren et al. 2005). We assume that these conclusions may be valid even if different phthalates are used as plasticizers.

Table 21: Comparison of summary concentrations of fifteen phthalates in samples taken in 2006 and in 2008.

Sample – Place of testing	DBP	DEHP	Sum
Unit	µg/g	µg/g	µg/g
Dust analyses in 2006			
Prague: Office of Martin Bursík	20	10	45
Ústí nad Labem: Regional Authority building	84	810	964
Churáňov: Meteorological observatory	460	2400	**2912**
Ostrava: Regional Authority building	93	1900	**2103**
Dust analyses in 2008			
VYS 1: Flat without PVC	131	210	390.0
VYS 2: Building of the Regional Authority of the Vysočina Region	24	131	185.0
VYS 3: Kindergarten	187	969	**1184.3**
VYS 4: Dental office	156	2165	**2329.5**
VYS 5: Flat with PVC	74	1429	**1516.7**
VYS 6: Flat with PVC	18	193	215.6
PAR 1: Elementary school – dining room with PVC	38	2813	**2881.0**
PAR 2: Elementary school – staff room	30	397	490.7
PRA 1: Flat with PVC	40	208	312.9
PRA 2: Office of the Minister of Education	186	254	515.4

11. Development of Legislation

Phthalates are subject to the European chemical policy system, specifically the regulation known under the abbreviation REACH (Registration, Evaluation, Authorisation of Chemicals). Use of phthalates DEHP, DBP, and BBP, in toys in concentrations higher than 0.1 % by weight was not allowed since 1999 already. Further 3 phthalates, DINP, DIDP, and DNOP, were regulated in toys intended to be placed in the mouth (Entries 51, 52 of Annex XVII to REACH). This ban was valid according to Commission Decision 1999/815/EC, on the basis of Article 9 of Council Directive 92/59/EEC, initially, when it was adopted, for products intended for children under 3 years of age. This ban was renewed periodically till 2007, when a ban of phthalate presence in toys and childcare articles was adopted without age limitation. Any toy, placed on the European Union market, has to meet technical requirements (so-called essential safety requirements) laid down by European Directive 2009/48/EC (European Parliament and Council 2009) of June 18, 2009, on the safety of toys, implemented, in the Czech Republic, by Government Order No. 86/2011 Coll., dated March 9, 2011.

According to European Regulation 1223/2009 (European Parliament and Council 2009), that came into force on July 11, 2013, phthalates DEHP and DBP are banned in cosmetic products and preparations intended for body care.

On the basis of European Directive 2007/47/EEC, amending Directive 93/42/EEC concerning medical devices, medical devices must be clearly labelled that they contain substances toxic to reproduction (CMR substances). If medical devices intended, for example, to administer medicines, liquids, and blood, to body are used also for children, pregnant and nursing women, the manufacturer must provide justification for the use of toxic phthalates within the technical documentation (European Parliament and Council 2007).

The European legislation regulates also use of phthalates (BBP, DEHP, DBP, DINP, and DIDP) in plastic food packaging, on the one hand by their absolute value, that must not exceed 0.05 - 0.1 % by weight, and, on the other hand, by migration limits. It depends also on the kind of foodstuff, whether the packaging is in direct contact with the food, and whether single-use or multiple-use packaging is concerned.

The basic legal regulation concerning food packaging, valid in the Czech Republic, was Decree No. 38/2001 Coll. on hygienic requirements on products intended to come into contact with foodstuffs and foods. It was amended by Decree No. 271/2008 Coll. that came into force on August 15, 2008 (Válek and Petrlík 2014), and, later, by Decree No. 111/2011 Coll., that, however, did not regulate phthalates directly.

Decree No. 38/2001 Coll. banned use of the mentioned phthalates in materials coming into contact with foodstuffs (except DEHP for surface treatment of cork - max. 0.2 mg/dm^2). European Commission Regulation No. 10/2011 developed an older Regulation 1935/2004/EC, laying down that substances must not migrate from materials in amounts threatening health (ICBP 2008). Generally, concentrations up to 0.1 % by weight are allowed, as acceptable trace amounts (European Commission 2011).

In 2014 - 2015, authorisation of 7 phthalates took place. These substances were classified as very hazardous for human health and the environment, for the reasons of their effects as endocrine disruptors (they impact production and function of hormones). Of them, 4 phthalates - DEHP, DBP, BBP, and DIBP - were included into the so-called candidate list for authorisation. The candidate list includes chemical substances that represent high risk for human health and the environment and that will have to be authorised for specific use in situations where no alternatives exist only. Simultaneously, any EU Member State may submit a proposal for complete ban of use of these substances in the European Union.

In 2011 already, Denmark submitted a proposal for restriction of 4 phthalates classified as toxic to reproduction, on the basis of information on their cumulative negative effects on human health (Denmark 2011, The Danish EPA 2011). Denmark carried out an extensive

biomonitoring study, just in order to map the burden of the Danish population by phthalates. However, the European Chemical Agency (ECHA) rejected the Danish proposal in 2012, with the reasoning that the submitted study was not sufficient for determination of the risk for the whole European population. Simultaneously, Denmark was prohibited to ban phthalates on the national level (The Danish EPA 2013).

With a new regulation, entry 51 of Annex XVII to Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals within the framework of the European chemical policy has been changed as of July 2020. This new restriction introduces three important changes. Namely, restriction of phthalates was widened from three substances (DEHP, DBP, and BBP) to four, through addition of DIBP. Further, the restriction that concerned only toys and childcare articles originally, has been widened to all plastic products. Thus, according to the new restriction, DEHP, DBP, BBP, and DIBP, individually or in their sum, must not be present in a concentration higher than 0.1 % by weight in plasticized plastic products for children and childcare, but also in plasticized materials generally (European Commission 2018).

Last but not least, the Annex also includes legal definition of the terms „plasticized material", „prolonged contact with human skin", and „childcare articles", what may be important for proper interpretation of the new regulation.

It has to be noted that the regulation does not apply to products placed on the market before July 7, 2020, and also to articles for industrial or agricultural use, measuring devices for laboratory use, and articles for use in the open air, provided that they do not come into prolonged contact with human skin or mucous membranes, and, further, also to materials and articles intended to come into contact with food, medical devices, electrical and electronic equipment, and immediate packaging of medicinal products (European Commission 2018).

12. List of Abbreviations

BBP – benzyl butyl phthalate

BEP – bis(2-butoxyethyl) phthalate

CMR – carcinogens, mutagens and/or reproductive toxicants

DBP – dibutyl phthalate

DCHP – dicyclohexyl phthalate

DEHP – di(2-etylhexyl) phthalate

DEP – diethyl phthalate

DHXP – dihexyl phthalate

DIBP – diisobutyl phthalate

DIDP – diisodecyl phthalate

DINP – diisononyl phthalate

DMEP – bis(2-methoxyethyl) phthalate

DMP – dimethyl phthalate

DNOP – di-n-octyl phthalate

DNP – dinonyl phthalate

DOIP – bis(2-ethylhexyl) isophthalate

DPP – dipentyl phthalate

EU – European Union

Pb – lead

PVC – polyvinyl chloride

REACH – Registration, Evaluation, Authorisation of Chemicals

TBC – tributyl citrate

wt. % – weight percent

13. Annexes

13.1 Analysis of Toys and Other Products for Children from Belarus (2014)

13.1.1 Text Part

Arnika, together with the organisation Center for Environmental Solutions (CES), carried out extensive analyses of products from Belarus for presence of phthalates and heavy metals in children's toys and childcare articles. During the third, most extensive, phase of the project, 21 products were tested in 2014. Because some of the products were made of several plastic parts, in total 30 analyses were carried out. The results are summarised in Table 22. Photos of the tested parts are presented in Annex 13.4.2.

Products sent from Belarus were analysed for presence of phthalates and other plasticizers, namely DEHP, DINP, DBP, isophthalate DOIP, and adipate DEHA (bis(2-ethylhexyl) adipate) (Petrlík, Straková et al. 2014). Of the total tested 21 samples, 16 were toys, 2 childcare articles (samples Nos. 8a, 8b, 16a, and 16b), and 3 children's clothes (samples Nos. 2, 20, and 21). As follows from Table 22, all the tested samples contained at least one of the tested substances. Their contents were in the range from 16.1 to 56.2 wt. %. The highest phthalate content exceeded a half of the sample weight. Phthalate DEHP was found in 14 of the 30 tested samples, in amounts from 2.1 to 56.2 wt. %. Phthalate DINP was found in 3 of the 30 tested samples, in amounts from 3.6 to 20.8 wt. %. Phthalate DBP was found in 3 of the 30 tested samples, in amounts from 16.7 to 23.2 wt. %. Results of analyses for DOIP were positive in 13 of the 30 tested samples, in the amounts from 20.4 to 39.9 wt. %. And, finally, results of analyses for DEHA were positive in 1 of the samples, containing 11.1 wt. % of this substance

To conclude, phthalates DEHP, DINP, and DBP were present in 18 of the 30 tested samples in amounts exceeding 0.1 wt. %. In the remaining 12 samples, isophthalate DOIP was found only. This substance, in contrast to the three above-mentioned phthalates, was not subject to a ban in the EU in the time of the testing (Petrlík, Straková et al. 2014).

Table 22: Results of analyses of phthalates and other plasticizers in toys, products for children and childcare articles and clothes in Belarus. Source: (Petrlík, Straková et al. 2014).

Sample	Sample description	DEHP	DINP*	DOIP	DBP	DEHA
1	2 animal toys KungFu Panda; any part of one of the animals	-	-	34.9	-	-
2	Pink raincoat; pink plasticized PVC of the raincoat	16.1	-	-	-	-
3	Rainbow inflatable ball; part of the ball made of PVC, without printing	-	-	-	16.7	-
4	Red-black inflatable toy; some plastic mix	11.7	4.7	-	-	-
5	Pink inflatable ball;	-	-	-	23.2	-
6a	Inflatable dolphin - body of the toy; plastic from which the dolphin itself is made	-	-	29.3	-	-
6b	Inflatable dolphin - inflation valve; inflation valve	-	-	39.9	-	-

7a	Barbie doll; head, body	-	-	23.2	-	-
7b	Barbie doll; shoes	-	-	33.1	-	-
7c	Barbie doll; handbag	-	-	30.2	-	-
8a	Orange swim vest; plastic from which the vest itself is made	-	-	24.2	-	-
8b	Orange swim vest; inflation valve	-	-	32.0	-	-
9a	Yellow floating duck - ring; plastic from which the ring itself is made (without printing)	2.5	-	20.4	-	-
9b	Yellow floating duck - ring; inflation valve	-	-	30.9	-	-
10	Baby doll; plastic part	-	20.8	-	-	-
11	Squeaky toy pink pig; unprinted part of the plastic	56.2	-	-	-	-
12a	Yellow inflatable ring with fruits (yellow); plastic from which the ring itself is made (without printing)	-	-	22.6	-	-
12b	Yellow inflatable ring with fruits (yellow); inflation valve	-	-	28.5	-	-
13	Puppet toys, three small pigs; plastic pig heads	52.3	-	-	-	-
14a	Blue-pink inflatable toy - hand; blue part (without printing)	22.8	-	-	-	-
14b	Blue-pink inflatable toy - hand; pink part (without printing)	18.8	-	-	-	-
14c	Blue-pink inflatable toy - hand; inflation valve	24.7	-	-	-	-
15	squeaky toy yellow fish; without printing	52.6	-	-	-	-
16a	Inflatable green swim sleeves; plastic from which the sleeves themselves are made (without printing)	21.4	-	-	-	-
16b	Inflatable green swim sleeves; inflation valve	21.0	-	-	-	-
17	2 dolls Pinocchio; one of the dolls (plastic without printing)	-	-	29.9	-	-
18	Child transparent bag with blue flowers; plastic of the bag	17.0	-	-	-	-
19	Big red inflatable toy - cow; plastic of the toy	-	-	-	19.9	-
20	Yellow T-shirt with printing - Skate Academy; plastic film of the printing	28.7	-	-	-	-
21	T-shirt with printing - Lion; plastic film of the printing	2.1	3.6	-	-	11.1

[-] … < 0.05 % by weight.

* … in relation to the DNOP response factor.

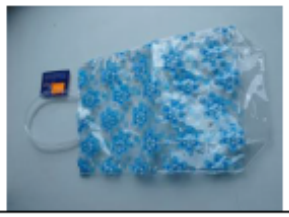
13.1.2 Photos and Overview of Analyzed Samples from Belarus

Sample number	Description	Country of origin, manufacturer	Parts tested for phthalate contents
1	2 animal toys KungFu Panda 		Any part of one of the animals
2	Pink raincoat 		Pink plasticized PVC
3	Rainbow inflatable ball 		PVC – part of the ball without printing
4	Red-black inflatable toy 		Mixed plastic sample
5	Pink inflatable ball 		-

6a	Inflatable dolphin – body of the toy 	China	Plastic from which the dolphin itself is made
6b	Inflatable dolphin – inflation valve (photo – see 6a)		Inflation valve
7a	Barbie doll 		Head, body
7b	Barbie doll 		Shoes
7c	Barbie doll (photo see 7b)		Handbag
8a	Orange swim vest 	China	Plastic from which the vest itself is made
8b	Orange swim vest (photo see 8a)	China	Inflation valve

9a	Swim ring – yellow duck  		Plastic from which the ring itself is made (without printing)
9b	Swim ring – yellow duck (photo see 9a)		Inflation valve
10	Baby doll 		Plastic part
11	Squeaky toy – pink pig 		Unprinted part of the plastic
12a	Yellow inflatable ring with fruits (yellow) 		Plastic from which the ring itself is made (without printing)
12b	Yellow inflatable ring with fruits (yellow) (see photo at 12a)		Inflation valve

13	Puppet toys „Three little pigs" 		Plastic pig heads
14a	Blue-pink inflatable toy - hand 		Blue part (without printing)
14b	Blue-pink inflatable toy - hand (see photo at 14a)		Pink part (without printing)
14c	Blue-pink inflatable toy – hand (see photo at 14a)		Inflation valve
15	Squeaky toy – yellow fish 		Plastic without printing
16a	Inflatable swim sleeves, green 		Plastic from which the sleeves themselves are made (without printing)

16b	Inflatable swim sleeves, green (see photo at 16a)		Inflation valve
17	2 dolls Pinocchio 		One of the dolls (plastic without printing)
18	Child transparent bag with blue flowers 		Plastic of the bag
19	Inflatable toy – big red cow 		Plastic of the toy
20	T-shirt with printing, yellow – Skate Academy		Plastic film of the printing
21	T-shirt with printing, with lion		Plastic film of the printing

13.2 Medical Equipment (2012) – Photos

Compat GO Set Portable

Connecting infusion tube CHIRALINE

Universal tube GAMAPLUS

Heidelberg extension tube

Extension tube KD Line

13.3 Childcare Articles (2012) – Photos

13.3.1 Nasal Aspirators

GAMA - nasal aspirator for infants

OTRIVIN – nasal aspirator – transparent tube

NOSÁTKO – nasal aspirator

ARIANA BABY VAC

13.3.2 Diaper Changing Pads

Akutu: Diaper changing pad

Méďa: Soft diaper changing pad on a chest of drawers

NOSÁTKO – nasal aspirator

ARIANA BABY VAC

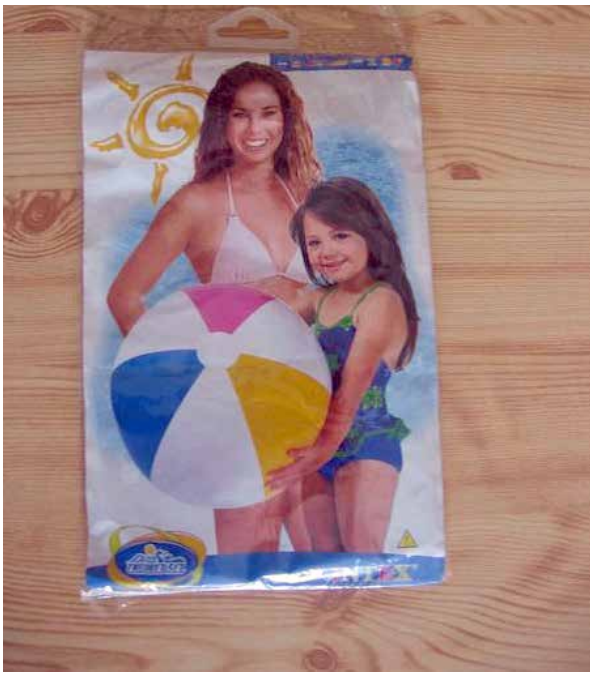
NOSÁTKO – nasal aspirator

ARIANA BABY VAC

13.4 Toys (2007) - Photos

Sample No. 1:
PVC packaging for blocks. Bought in Kotva department store in Prague. Importer: ADC Blackfire Entertainment, manufactured by the company GALT, UK.

Sample No. 3:
Inflatable ball, the tested part was the ball plug. Bought in Kotva department store. Importer: Alltoys spol s.r.o. Praha, made in China.



Sample No. 2:
Turtle toy. Bought in Tesco department store on Národní Třída street in Prague. Importer: Alltoys spol. s.r.o. Praha, made in China.

Sample No. 4:
PVC packaging for a toy „book". Bought in Tesco department store on Národní Třída street in Prague. Manufacturer: Simba Toys GmbH, Germany.

Sample No. 5:
Inflatable animal. Bought in Kotva department store. Importer: Alltoys spol.s.r.o. Praha, made in China.

13.5 Loom Band Charms and Scoubidou Strings (2014) – Photos

Loom band charms

Scoubidou strings

13.6 Wallpapers and Floor coverings (2010)

13.6.1 Photos of Analyzed Wallpapers

Sample 1:
Adhesive foil "Mickey Mouse, Dumbo, Donald Duck"

Sample 2:
Adhesive foil "Winnie the Pooh"

Sample 3:
Wallpaper "with parrots"

13.6.2 Detailed Information About Analysed Articles

Sample No. 1
Name: Polo 5808014
Total thickness: 0.8 mm
Thickness of the wear layer: 0.12 mm
Type: roll having the width of 2 m
Company: Sklepy Komfort S.A.
Shop: Ostrava, Shopping Centre Futurum, Varenská 3309/50, 70200 Ostrava
Date of purchase: December 13, 2011

Sample No. 2
Name: Sawa Step 3081 D
Total thickness: 1.3 mm
Thickness of the wear layer: 0.15 mm
Type: roll having the width of 4 m
Company: Sklepy Komfort S.A.
Shop: Ostrava, Shopping Centre Futurum, Varenská 3309/50, 70200 Ostrava
Date of purchase: December 13, 2011

Sample No. 3
Name: Rodos 033
Total thickness: 2.8 mm
Thickness of the wear layer: 0.2 mm
Type: roll having the width of 4 m
Company: Sklepy Komfort S.A.
Shop: Ostrava, Shopping Centre Futurum, Varenská 3309/50, 70200 Ostrava
Date of purchase: December 13, 2011

Sample No. 4
Name: Flexar 471-05
Total thickness: 2 mm
Thickness of the wear layer: 0.8 mm
Type: roll having the width of 2 m
Company: Sklepy Komfort S.A.
Shop: Ostrava, Shopping Centre Futurum, Varenská 3309/50, 70200 Ostrava
Date of purchase: December 13, 2011

Sample No. 5
Name: d-c-fix 274-0007
Total thickness: 1.2 mm
Thickness of the wear layer: not stated
Type: self-adhesive square tiles, side length 30.4 cm, 11 pieces packed together
Company: Konrad Hornschuch AG, Weißbach
Shop: Bauhaus Ostrava, Janáčkova 22, Ostrava
Date of purchase: December 13, 2011

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