

Phthalates in articles on the Serbian market

SOFT plastic, HARSH truth



TRANSITION



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Executive Summary

Safer Chemicals Alternative (ALHem) from Serbia and Arnika from the Czech Republic conducted the analysis of the presence of phthalates in products for everyday use within the campaign “SOFT Plastic, HARSH Truth” with the aim of advocating the adoption of a phthalate ban/restriction in consumer products in Serbia. This analysis has been carried out with the financial assistance of the Transition Promotion Programme of the Ministry of Foreign Affairs of the Czech Republic.

The current study is part of ALHem’s activities focused on the monitoring of hazardous chemicals in consumer products available on the market of the Republic of Serbia with the aim of providing input to the faster transposition of EU legislation into the national legislation governing consumer safety for hazardous chemicals in products.

The purpose of the analyses carried out within the joint ALHem/ARNIKA project was to examine the presence in plastic products on the Serbian market of the following four phthalates: bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diisobutyl phthalate (DIBP). Laboratory testing of the content of phthalates was conducted in the “Milan Jovanović Batut” Institute for Public Health in August 2020.

The test results shows that these phthalates are found in 10 out of 36 samples (in concentrations above 0.1%), which represents one-third of the total number of articles tested, with the concentrations ranging from 0.16 to 18.15%. They have been found in school bag, girls’ bag, raincoat, children’s slippers, a PVC ladies’ makeup/toilet bag, PVC fabric tarpaulin, imitation leather, PVC wallpaper, and car mats. These products

were bought in well-known shops and were produced mostly by EU and domestic producers with registered trademarks.

Since 8 July 2020, in the EU there has been a restriction on placing on the market consumer products that contain these four phthalates in a concentration above 0.1%. These substances are the most commonly used plastic softeners, and have been **proved to have toxic effects on reproduction (they can be harmful to fertility and to a foetus) and they can lead to disturbances in the functioning of the hormonal system (endocrine disruptors).** The restriction proposal took into account the cumulative effects and combined exposure to these four phthalates from different articles and confirmed the inadequately controlled risk to human health from exposure to these phthalates in products.

However, this restriction has not yet been transposed into the Serbian legislation and products that contain these four phthalates can be legally placed on the Serbian market. The whole campaign is being run to speed up the adoption of the new regulation related to the restrictions on phthalates and other restrictions related to chemicals in Serbia.

It is alarming that phthalates are found in products used mostly by children and young people. In addition, the four phthalates that were tested are found in raw materials such as PVC fabric and imitation leather that can be used for different purposes by industry and consumers, such as for indoor children’s playgrounds, furniture, fashion accessories, etc. and then exposure could be significant.

The other purpose of this campaign is to check the fulfilment of the companies’ obligation to inform consumers if the products they buy contain substances of very high



concern (SVHCs). These four phthalates are on the EU and Serbian Candidate List of SVHCs [1], which means that if they are present in a product in a concentration of more than 0.1%, producers, importers, distributors, and retailers of the product are obliged to submit information at a consumer's request that is sufficient for the safe use of that product, at least the name of the substance.

Although we found these phthalates in concentrations above 0.1% in ten products (which fall under the 'right to information') and sent SVHC requests, we did not receive information from any of the suppliers for these ten products. Bearing in mind that we did not receive any response and that this obligation is explicitly stated in the Serbian legislation, as are the corresponding penalty provisions, the competent authority should consider how to encourage companies to fulfil this obligation.

The question of time is very important in order not to allow the domestic market to become a market for products that are banned

in the EU. Therefore, we call upon the Ministry responsible for the environment in Serbia to speed up the process for the adoption of the legislation to restrict phthalates by transposing EU Regulation 2018/2005 from December 2018 [2], as well as to update the Candidate List of SVHCs.

It is necessary to continue raising awareness about SVHCs in products amongst suppliers and about their obligations related to the provision of information at consumers' request pursuant to Article 27 of the Law on Chemicals. However, if consumers do not get information, they should refer to the competent environmental inspectorate in order to ensure the application of the prescribed legal measures. By exercising this right, consumers can influence the producers, importers, distributors, and retailers by indicating the need to procure products that are free of these substances.

Introduction

Two NGOs, the Serbian ALHem (Safer Chemicals Alternatives) and Czech Arnika, present the results of a new study carried out with financial support from the Transition Promotion Programme of the Ministry of Foreign Affairs of the Czech Republic and the Global Greengrants Fund with the goal of highlighting the importance of disclosing information on hazardous chemicals in consumer products.

The current study is part of ALHem's activities focused on the monitoring of phthalates in consumer products available on the market of the Republic of Serbia, with the aim being to provide input to the faster transposition of EU legislation into the national legislation governing consumer safety for hazardous chemicals in products.

In the last five years, ALHem has conducted two campaigns ("The Fight to Know!", "CRY-GAME") dealing with testing products for their phthalate

content in products from the Serbian market. Both campaigns showed that everyday consumer products contained phthalates, which are harmful to health and the environment^{1 2} [3, 4].

The good news is that consumers have the right to know from the seller or manufacturer of a product whether it contains substances that are harmful to human health or the environment. Under the European chemicals' regulation „REACH“, as well as the Serbian Law on Chemicals, these substances have been compiled into a „Candidate List“ since 2009 and fall under what is called the 'right to information'. On the request of a consumer, both producers and sellers are obliged to provide information on such substances of very high concern and instructions on the safe use of the product. [5]

The other purpose of this campaign "SOFT Plastic, HARSH Truth" is to check the fulfilment of the companies' obligation to inform consumers if the products they buy contain substances of very high concern.

¹ In 2015-2016 ALHem coordinated the "The Fight to Know!" campaign, which was focused on the presence of phthalates in consumer products. The campaign was part of the project "Strengthening capacities and strategic partnership for safe management of chemicals in the Republic of Serbia"², which aimed at checking the practical implementation of legal provisions related to providing information about the presence of substances of very high concern (SVHCs) in products and the promotion of consumers' rights to obtain such information.

² In 2018-2019 ALHem carried out the "CRY-GAME" campaign with support from IPEN's Chemicals in Products Programme, which focuses on raising consumer awareness of restricted phthalates in toys and childcare articles and promotes consumers' right to know about chemicals in children's toys to help them make informed choices.

Legislation

The European Union has restricted certain phthalates in toys and childcare articles since 1999. Phthalates are regulated under the REACH Regulation on the Registration, Evaluation, Authorisation, and restriction of CHemicals [5] and several other regulations. On December 2018, the EU published a new Regulation (EU 2018/2005) related to phthalates [2] that expands the number of restricted phthalates and expands the scope of the restriction on the use of phthalates in toys and childcare articles to other articles.

The restriction of chemicals is transposed into the Serbian legislation from the EU REACH Regulation (Law on Chemicals [6] and the Bylaw related to restriction [7]) and phthalates in toys and childcare articles are restricted. However, the restriction of phthalates in plasticised materials in other articles has still not been transposed into the Serbian legislation. Serbia should restrict phthalates in other articles in the same way as it is restricted in the EU as soon as possible. Bearing in mind the widespread usage of phthalates, an appropriate enforcement strategy for market surveillance should be found.

REACH and the Serbian Law on Chemicals

The European Union REACH Regulation on the Registration, Evaluation, Authorisation, and restriction of CHemicals entered into force in 2007, with the aim of ensuring a high level of protection for human health and the environment, as well as the free circulation of substances on the internal market and the enhancement of competitiveness and innovation.

At this stage, the Serbian legislation is partially aligned with the REACH requirements. The Law on Chemicals has been harmonised with parts of REACH by taking over certain obligations, including provisions defining centralised

Since 8 July 2020 in the EU restrictions have been in existence on placing on the market articles containing the four phthalates (DEHP, BBP, DBP, and DIBP) in a concentration equal to or above 0.1% by weight individually or in any combination in any plasticised material.

procedures of registration, evaluation, and authorisation conducted by the European Chemicals Agency (ECHA).

The Serbian Law on Chemicals provides measures and conditions for: managing the safety of chemicals; classifying, labelling, and packaging; importing and exporting controlled substances; obtaining licences and permits for use; restrictions on substances, and the enforcement and monitoring of chemicals. It also controls the integrated chemical register.

Phthalate restrictions

The restrictions are regulatory measures of the REACH Regulation to protect human health and the environment against unacceptable risks posed by chemicals.

In Annex XVII of the REACH Regulation there is a list of restricted chemicals. In 1999 REACH Annex XVII entry 51 restricted three phthalates, (bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP) in plasticised materials of toys and childcare articles. The new amendment to Annex XVII from the end of 2018 expands the restricted phthalates by newly adding diisobutyl phthalate (DIBP) and expands the scope of the products. Besides toys and childcare articles, other articles containing these four phthalates as plasticised

materials are also restricted, including articles used in indoor environments or in the open air which come into contact with human mucous membranes or have prolonged contact with human skin. This restriction entered into force in the EU this year, on 8 July 2020.

The proposal for the restriction took into account the cumulative effects and combined exposure to these four phthalates from different articles and confirmed that there is an inadequately controlled risk to human health resulting from exposure to these phthalates in articles.

Along with these phthalates, three more phthalates are restricted in the EU: DIDP (di-isodecyl phthalate), DINP (di-isononyl phthalate), and DNOP (di-n-octyl phthalate). Toys and childcare articles which can be placed in the mouth by children and contain these three phthalates in a concentration greater than 0.1% by weight of plasticised material are not to be placed on the market.

The restriction related to phthalates in toys and childcare articles has been transposed into the Serbian legislation; however, restrictions related to phthalates in other articles still do not exist. Annex I provides the texts of the restrictions on phthalates in Serbia and the European Union.

Article 33 of REACH and Article 27 of the Serbian Law on Chemicals

Article 33 of REACH states that: *“On request by a consumer any supplier of an article containing a substance meeting the criteria ...”* for definitions of SVHC substances *“ .. in a concentration above 0.1% by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article, including as a minimum the name of that substance.”* [5] The information must be made available on request within 45 days, free of charge.

Article 33 applies to most solid objects such as clothing, furniture, toys, or electronics offered for consumer use. In the case of "non-solid" products such as food, medicines, cosmetics, cleaning agents, or paints, the obligation to provide information applies only to their packaging. In brief, it applies to all uses of SVHC substances as it is defined in the scope of Article 1 of REACH [5].

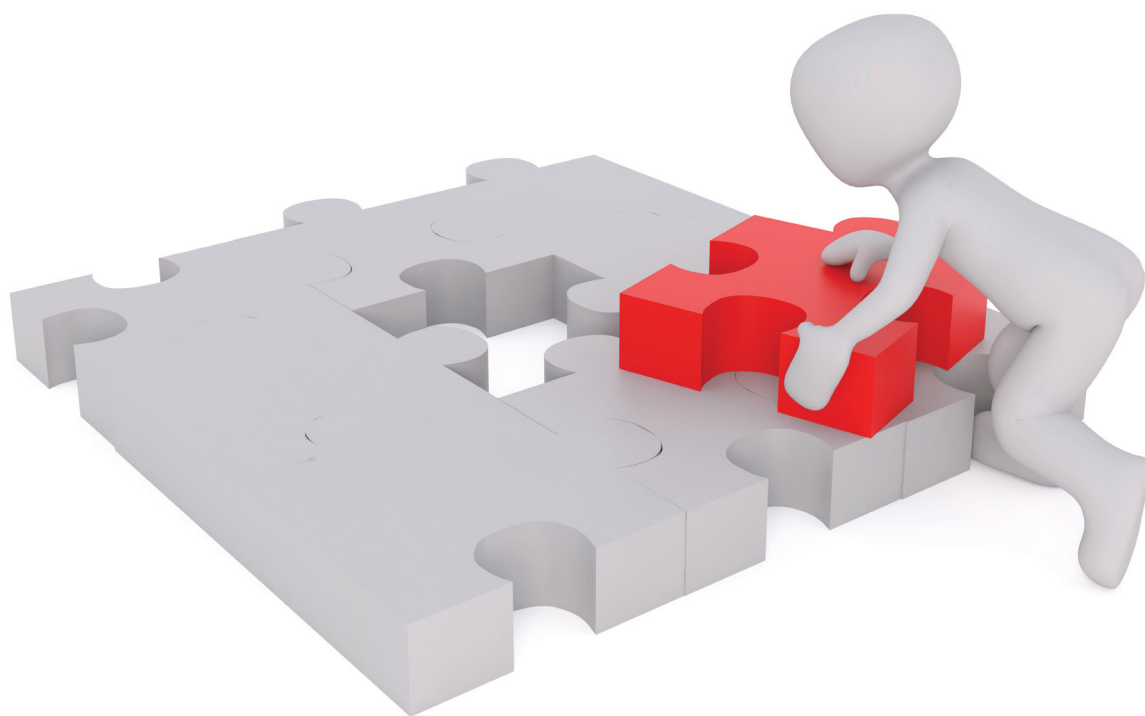
If a product contains an SVHC substance, this does not necessarily constitute an acute hazard, as the substance may be chemically bound, for example, inside an article. However, during the life cycle of consumer articles certain substances may be released into the environment and might – as a result of their possible undesirable properties – lead to (cumulative) effects some day. Consumers may request information about the presence of such substances and avoid them.

The same obligation is prescribed in the Serbian Law on Chemicals and companies are obliged to inform consumers if an article contains SVHC substances. Companies at every stage of the supply chain should pass on information related to SVHCs in compliance with the Serbian Law on Chemicals. Information on SVHCs must be disseminated along the supply chain and also ultimately made available to the public and consumers. Explicitly, all companies selling articles that contain above 0.1% of SVHC substances in Serbia must comply with the national legislation and inform consumers at their request about the presence of SVHC substances in articles [6].

Candidate List

Certain chemical substances are defined in the REACH Regulation as SVHCs (Substances of Very High Concern). The SVHCs are listed in the "Candidate List", which is updated twice a year and currently contains 209 substances (September 2020). These substances are candidates for the authorisation process under REACH, i.e. their use might be limited to certain applications. In addition, REACH stipulates that these chemicals should be progressively replaced by suitable alternative substances or technologies where economically and technically viable. SVHCs are proven to be: carcinogenic; reprotoxic; mutagenic; endocrine disruptive; persistent, bioaccumulative and toxic; very persistent and very bioaccumulating or of similar concern.

Substances of Very High Concern are defined in the Serbian legislation as well and the chemicals from the European "Candidate List" of SVHCs have been transposed into one of the Serbian by-laws [1], which currently contains



181 substances (September 2020). That list in the by-law is not updated regularly.

Substances of Very High Concern include, inter alia, certain substances from the phthalate group (esters of phthalic acid and aliphatic alcohols), which are the most commonly used plastic softeners, and have been proved to have toxic effects on reproduction (they can be harmful to fertility and to the foetus) and proved to be endocrine disruptors.

The four phthalates tested during this campaign are listed in both the EU and Serbian Candidate Lists.

In addition to the four phthalates that were tested, there are also other phthalates in the Candidate List; at the moment there are 11 phthalates and a table showing these phthalates is included in Annex II.

Substances of very high concern and waste

The EU Waste Framework Directive requires companies to submit their data on substances of very high concern (SVHCs) in their articles in the SCIP database as of 5 January 2021. Consumers and waste operators can access and use the data from February 2021 onwards.

The purpose of this database is to know more about the hazardous chemicals in products so that they can be safely recycled. The increased knowledge protects workers, citizens, and the environment, helps consumers make safer choices, and encourages industry to replace hazardous chemicals with safer ones.

To our knowledge, the establishment of a similar database in Serbia is not yet being considered.

Phthalates

Phthalates are the most commonly used plasticisers in the world. In Europe, about one million tonnes of phthalates are produced each year – about 80% of the entire plasticisers market – of which approximately 95% are used to make flexible polyvinyl chloride (PVC) [8]. PVC is the second most commonly- used plastic in the world.

Phthalates can be found in a range of everyday items, including electrical cables, hoses, flooring, wall coverings, coated textiles, luggage, sports equipment, roofing membranes, pool liners, and footwear, as well as medical devices such as tubing and blood bags. In addition, some phthalates are used in non-PVC applications such as coatings, rubber products, adhesives, and sealants.

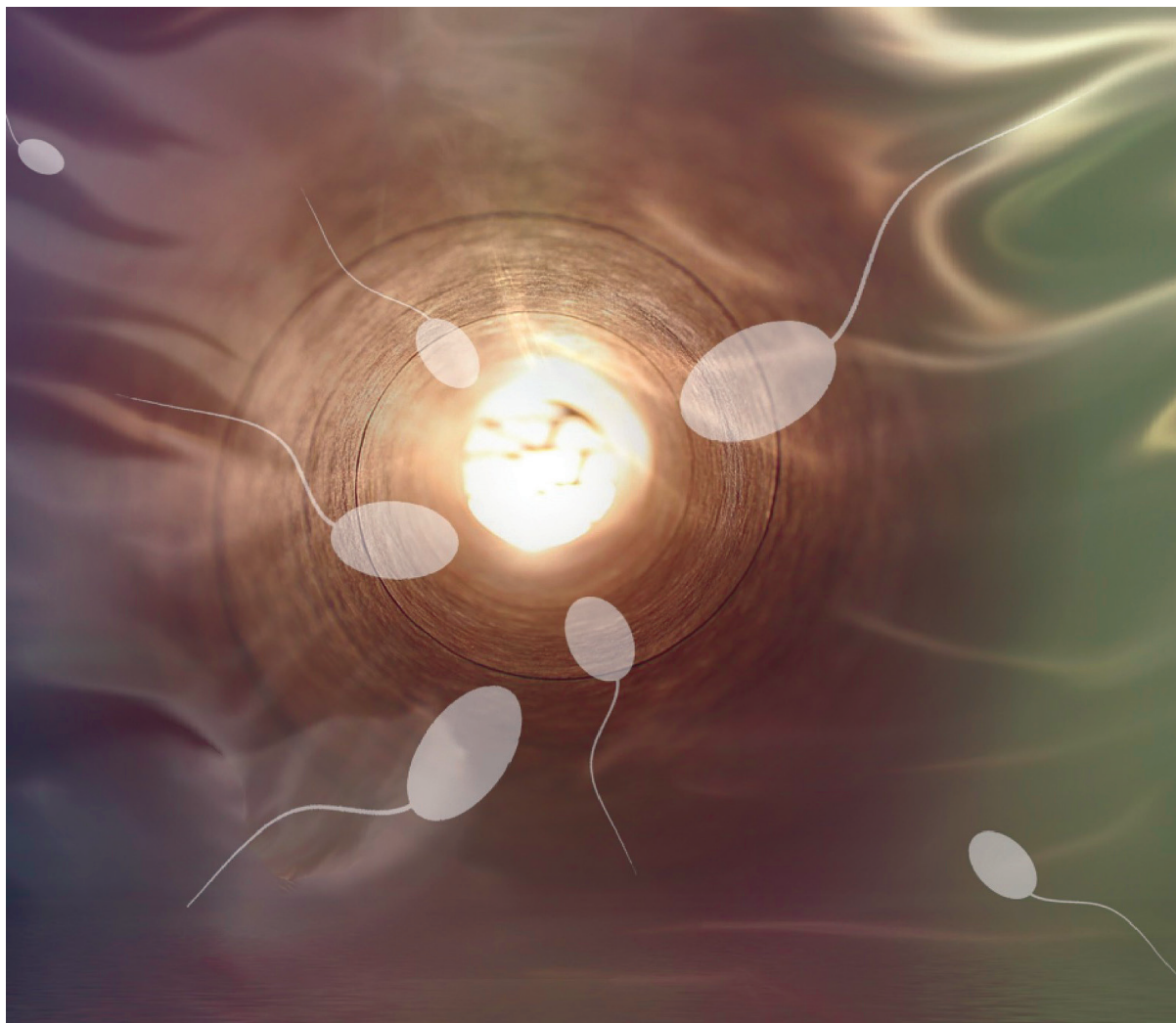
Phthalates can have an effect similar to hormones that disturb the functioning of the endocrine system. **Endocrine-disrupting chemicals** are substances that can impair the functioning of the endocrine system by taking over the role of hormones and blocking hormone receptors, which can in turn affect the development and functioning of the body. The effects of endocrine-disrupting substances depend greatly on when they enter the body. They are particularly harmful if they enter the body during in critical phases of life, such as pregnancy (when they can influence the development of the foetus), early childhood, and adolescence. During these critical developmental periods it is necessary to take special measures to protect people against exposure to, and the effects of,

Phthalates are substances that have proven toxic effects on reproduction: they have harmful effects on fertility and foetuses, and some – including DEHP, DBP, BBP, and DIBP – have been proved to disturb the functioning of the endocrine system; these phthalates are known as Endocrine-disrupting Chemicals (EDCs).

endocrine-disrupting substances, as even very small doses can be harmful for development. It is therefore very important to pay attention to articles that can contain phthalates.

Some phthalates have been shown to be **harmful to reproduction**, such as diethylhexyl phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), and diisobutyl phthalate (DIBP). In children, for example, they can interfere with sexual maturation. The exposure to hormone-like substances is also held responsible for the declining fertility of men which has been observed in Europe for decades. For example, the plasticisers mentioned above show anti-androgenic effects such as reduced testosterone production and can have a damaging effect on testicular function. Also, some phthalates used to replace regulated ones were found to be toxic to reproduction. Bis(2-ethylhexyl) isophthalate (DOIP)³, found in some consumer products [10-12], as well as in plastic marine debris [13], belongs to this group.

³ This phthalate was classified among “Substances predicted as likely to meet criteria for category 1A or 1B carcinogenicity, mutagenicity, or reproductive toxicity;” by 9. ECHA. Substance Infocard: Bis(2-ethylhexyl) isophthalate. 2019 04/07/2019 [cited 2020 10/10/2020]; Available from: <https://echa.europa.eu/cs/substance-information/-/substanceinfo/100.004.826>.



Children are more sensitive to exposure to dangerous chemicals than adults. This is due to a larger skin surface in proportion to their weight, greater proportional lung capacity, and a faster metabolism. As a consequence, children can ingest dangerous chemicals at faster rates than adults at a time when their immune and neurological systems are still developing.

A study carried out by the German Federal Environment Agency between 2003 and 2006, in which 1790 children aged between three and 14 years were examined, revealed alarming results, particularly for plasticisers. Metabolites of selected plasticisers were found in the urine of almost all children, in some cases in considerable concentrations [14].

These harmful chemicals **do not bind to polymers** (such as PVC) and are gradually **released over time**. Phthalates **enter the body** mainly through **food**, but also through **the air we breathe** or through **direct contact with the skin**.

Consumers can be exposed to substances like phthalates from many products in everyday use, including kitchen and bathroom articles, school accessories, imitation leather furniture, floor covers, vinyl wallpaper, shoe soles, electric and electronic devices, cables, and office equipment, as well as toys, baby equipment, and other products for children.

Phthalates are manufactured by reacting phthalic anhydride with alcohol(s) ranging from methanol and ethanol (C1/C2) up to tridecyl alcohol (C13). Ortho-phthalates are broadly divided into two main distinct groups: low-molecular-weight and high-molecular-weight ortho-phthalates with different applications, classifications, and legal requirements.

High-molecular-weight or high ortho-phthalates include those with 7-13 Carbon atoms in their chemical backbone, which gives them increased permanency and durability. The most common types of high ortho-phthalates



include Di-isononyl phthalate (DINP), Diisodecyl phthalate (DIDP), and other phthalates.

Even though the use of phthalates as plasticisers has decreased somewhat – mainly in the European Union – as a result of legislative actions measures, phthalates such as DINP, DPHP, and DIDP are still produced and used in many applications in the EU and represent just over 50% of the European plasticisers market [8]. In the rest of the world, DEHP continues to be the dominant plasticiser, even though its share of the market has decreased in recent years. Even so, DEHP accounted for one third of global plasticiser production in 2017, with the bulk of production in Asia [15]. It is still also produced in some EU countries, for example by the DEZA company, based in the Czech Republic.

Precautionary restrictions for toys and child-care articles which can be placed in the mouth exist for the high-molecular-weight phthalate

Di-isononyl phthalate (DINP), Di-n-octyl phthalate (DNOP) and Diisodecyl phthalate (DIDP)⁴ because of effects on the liver at high doses observed in rat studies. According to the SIN List⁵ for DINP, reprotoxic effects and effects on development have been reported and it is a suspected endocrine disruptor. Diisodecyl phthalate (DiDP) is a substance that has endocrine-disrupting properties. Exposure to diisodecyl phthalate in vivo has led to disturbed reproduction and development in rodents, daphnia, and fish. There is in vitro evidence of thyroidogenic activity and in vivo and in vitro evidence of oestrogenicity.

Plasticisers are marketed in high volumes and Di(2-ethylhexyl) phthalate (DEHP) is frequently detected in the environment and human populations. Currently, Diisononyl phthalate (DINP) is the plasticiser with the highest levels in suspended particulate matter (SPM)

⁴ They have all been registered for REACH and do not have harmonised classification for health and environmental effects, and nor are they on the Candidate List for Authorisation.

⁵ <https://sinlist.chemsec.org>

samples from the German Environmental Specimen Bank (ESB) [16].

The historic view

The development of cellulose nitrate plastic in the mid-19th century led to the patenting of the first plastics softener, called “Castor oil”, in 1856. Within twenty years a substance known as camphor became favoured as a softener over Caster oil in the production of cellulose nitrate plastics. Phthalates were first used in 1920, and very soon replaced camphor, which was volatile and characterised by its intense smell. The development in the 1930s of one particular plastics phthalate group (di(2-ethylhexil), commonly referred to as DEHP, revolutionised the PVC industry. DEHP remains in common use today.

PVC

Phthalates as plasticisers are crucial for polyvinyl chloride (PVC) plastics. Without phthalates

(or other plasticisers) added to them, these plastics would be stiff and brittle. Soft PVC is also a major source of environmental contamination with phthalates. It is also one of the most problematic plastics in relation to its impacts on the environment in all life cycle phases: production, use, and end-of life product management [17-20]. Its evaluation, commissioned by the European Commission in 2004, stated that: “From a PVC life cycle perspective, the production of stabilisers and plasticisers plays a significant role” [21]. Phthalates may also pose risks in recycled products made from soft PVC as they are either not destroyed during recycling processes and/or may be changed to volatile organic compounds (VOCs) such as 2-ethylhexanol, causing respiratory irritation [22-24]. Phthalates and/or their metabolites were, for example, analysed in roofing material from recycled soft PVC cable coatings [25].



Results

Methods used

At various retailers (Europe-based companies, Serbian companies, and well-known brands/chains) simple articles, which preferably consist of only one or two different materials (plastic products, mostly PVC, that are not toys/child-care articles) were purchased.

A total of 36 samples were subsequently tested for phthalates in an external accredited analytical laboratory. The types of products selected for the determination of the content of phthalates are given in Table 1.

The products were analysed for the **presence of four phthalates**, bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl

butyl phthalate (BBP), and diisobutyl phthalate (DIBP), in products on the Serbian market. These four phthalates were chosen as they have been the subjects of broad restrictions in the EU since 8 July 2020 (see the section on Legislation).

The cut-off value for the content of each phthalate is 0.1% (m/m).

The restriction on phthalates in the REACH Regulation stipulates that articles shall not be placed on the market if they contain the phthalates that were tested in a concentration equal to or greater than 0.1% by weight (individually or in any combination of the phthalates listed in Table 2) of the plasticised material in the article.

Table 1. Types of products to determine the content of phthalates.

Article's type	Number
School supplies (notebooks, pencil box, school bags)	4
Clothes, footwear, accessories (children's wallet, girl's bag, T-shirts, children's umbrella, case for glasses, toilet-make-up bags/fashion accessory, gumboots, raincoats, children's slippers)	16
Household and recreational equipment, other (non-slip bathmat, dining table mats, inflatable swimming accessories, flexible washbasin waste pipe, PVC shower hose, PVC fabric tarpaulin, gymnastic mats made with PVC fabric, imitation leather fabric, transparent PVC foil for restaurants and balcony, self-adhesive PVC foil)	16
Total	36

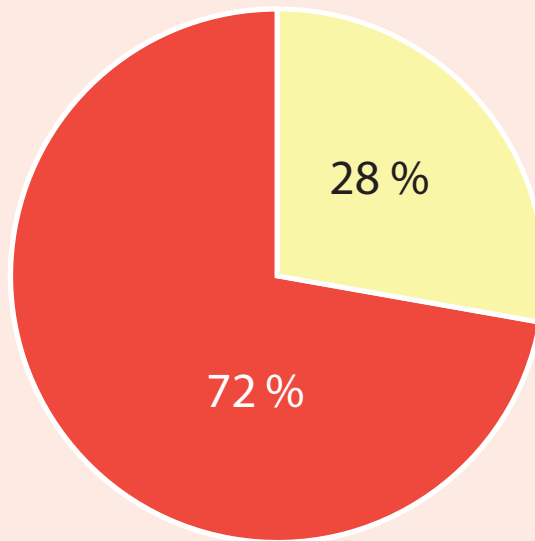
Table 2. Tested phthalates

	Substance	EC number	CAS number
1	Bis(2-ethylhexyl) phthalate (DEHP)	204-211-0	117-81-7
2	Dibutyl phthalate (DBP)	201-557-4	84-74-2
3	Benzyl butyl phthalate (BBP)	201-622-7	85-68-7
4	Diisobutyl phthalate (DIBP)	201-553-2	84-69-5

Fig. 1. Results of lab tasting of phthalates in samples

72% samples do not contain the phthalates that were tested in concentration above 0.1 %

28 % samples contain the phthalates that were tested in concentration above 0.1 %



That means if the article contains plastic parts and paper (e.g. a notebook with plastic covers) phthalates are examined only in the plastic part of the article and the concentration is calculated only for that plastic part.

Laboratory analyses of the content of phthalates were conducted in the "Milan Jovanović Batut" Institute for Public Health in August 2020. The laboratory is accredited by the Accreditation Body of Serbia according to the SRPS ISO/IEC 17025 standard and has accredited methodology for determining the content of phthalates in product samples, i.e. consumer goods; it is technically equipped for analysing the content of phthalates in products made of plasticised materials.

The samples were prepared and analysed according to the accreditation documents: VDM-98, which is defined within the Accreditation Scope 01-130 with the following elements: determining the content of softeners (Di-butyl benzyl phthalate, Di-butyl phthalate, Di-(2-ethylhexyl)phthalate, Di-n-octyl phthalate, Di-isononyl phthalate) applying the HPLC/DAD technique (Test Method: CPSC-CH-C1001-09.3 Standard Operating Procedure for Determination of Phthalates, 1 April 2010). The methodology is accredited for children's toys and plastic materials, as well as for items that come in contact with food, for the

range of 0.01% to 20% (m/m). The test results are presented in the report as a percentage content of phthalates.

Results for the phthalates that were analysed in selected products

Phthalates in concentrations above 0.1% were found in ten of the 36 samples, i.e. almost one-third of the articles tested for phthalates, especially the phthalate DEHP (see table), with concentrations ranging from 0.16 to 18.15%.

Four of the phthalates that were analysed as plasticisers were found in:

- school bag,
- girl's bag,
- girl's raincoat,
- children's slippers,
- PVC lady's makeup/toilet bag,
- PVC fabric tarpaulin,
- artificial leather,
- self-adhesive PVC foil,
- car mats.

It is alarming that phthalates are found in products used by children and young people. Another important observation is that phthalates are found in raw materials such as fabrics that can be used for different purposes by

industry and consumers. In addition, some Serbian companies producing clothing and fashion accessories, as well as footwear, are selling products with phthalates.

The retailer whose fabric (imitation leather) contained 18% of the plasticiser DEHP even claimed that this fabric was EKO leather.

Annex III includes a table with the phthalate content in the samples that were tested.

This campaign focused on finding the four banned phthalates, DEHP, DBP, BBP, and DIBP, in articles; the presence of the other high-molecular-weight phthalates was not examined because the main aim of this campaign was to examine the presence of phthalates that are banned in the EU in articles placed on the Serbian market.

However, alternatives to the four phthalates that were tested could be high-molecular-weight phthalates that have some properties of concern. In a similar campaign (ALHem "The Fight to Know!" campaign) that was run in 2015-2016 phthalates from the SVHC List in a concentration above 0.1% were identified in a total of 24 samples, of which six were cable samples and three were PVC floor coverings. In addition to these two types of products in six samples (four floor coverings and two cables) that were negative for the presence of phthalates from the SVHC List, the presence of DINP and DIDP was demonstrated. The observed percentage of DINP in these samples ranged from 13-26%, while the percentage of DIDP was below 0.5%.

Some other phthalates used as plasticisers replacing DEHP, for example, such as DOIP,

were found in high concentrations in consumer products in some other European countries [10, 12, 26], as well as being detected in products that were also sold outside Europe [11] and/or in plastic marine debris [13]. This phthalate is highly toxic for aquatic life [9].

The levels of phthalates in soft PVC products measured in previous reports show that the content of phthalates can reach very high levels, up to 41% [27] and 56% [12], respectively. It has to be noted that those levels of DEHP were measured in PVC products several years before the current restrictions in the EU were introduced.

Limitations of the analyses in our study

This study focused on the presence of four banned phthalates, DEHP, DBP, BBP, and DIBP, in articles, and the presence of other phthalates was not examined because the main aim of this campaign was to examine the presence of phthalates that are banned in the EU in articles placed on the Serbian market.

If the laboratory ordered to conduct the analyses for this campaign did not find the selected phthalates in some of the products at significant levels, it does not mean they are phthalate-free. It is also worth noting that the unregulated phthalates can cause potential harm to human health and the environment, as demonstrated in some other studies [9, 28-30].

Our focus was limited not only by the purpose but also the limited resources available and the constraints imposed by the COVID-19 situation.

Communication with companies – results

(consumers' right to information)

As already elaborated above, the EU and Serbian legislation (Article 33 of the REACH Regulation and Article 27 of the Law on Chemicals) prescribes that consumers have the right to know from the seller or manufacturer of a product whether it contains substances that are harmful to human health or the environment. These substances have been compiled in a list and fall under what is called the 'right to information'. This list includes the four phthalates that were tested, and other phthalates listed in Annex II. At the request of a consumer, both producers and sellers are obliged to provide information on such "Substances of Very High Concern" and instructions on the safe use of the product.

During the campaign, when we purchased the articles, they were scanned with the Scan4Chem app and an SVHC request was sent to the seller/producer. If no feedback was received from companies within 30 days of our SVHC request, they were automatically reminded again by the application. Requests for information were sent by members of different NGOs in Serbia.

We **received only three answers for three products from companies**. All the companies replied that the articles in question did not contain SVHCs. We did not find the phthalates that were tested in these three articles; however, we did not test the articles for all the SVHC substances in the Candidate List.

Although **SVHCs** (the phthalates that were tested) in concentrations above 0.1% were found **in ten articles that were tested**, and these products therefore fall under the 'right to

Sellers/producers of ten tested articles in which **SVHCs** (the phthalates that were tested) in concentrations above 0.1% were found did not respond to consumer requests for information although they fall under the 'right to information' obligation according to the legislation.

information', we **did not receive information about SVHCs from any of the sellers/producers** of these articles.

Annex IV gives the SVHC contents by article and the answers from the companies.

In general, there is a very low level of awareness about SVHCs among companies. On the other hand, the Serbian Law on Chemicals stipulates penalties for companies which do not respond to consumers if they sell/produce articles which contain SVHCs.

Several companies responded that they need to connect their supplier to respond. However, companies should be informed in advance about the presence of SVHCs in products. Companies at every stage of the supply chain should pass information related to SVHCs in compliance with the Serbian Law on Chemicals. Information on SVHCs must be disseminated along the supply chain and also ultimately made available to the public and consumers. Explicitly, all companies selling articles that contain above 0.1% of SVHCs in Serbia need to comply with the national legislation and to inform consumers on request about the presence of SVHCs in products.

Recommendations

What is needed?

» **Government/ responsible ministry**

- » The ministry responsible for the environment should speed up the process for the adoption of the legislation to restrict phthalates by transposing Regulation (EU 2018/2005) from December 2018, which expands the number of restricted phthalates and expands the scope of the restriction of phthalates in toys and child-care articles to other articles.
- » All substances of very high concern that are already on the European Candidate List should be added to the Serbian list of SVHC substances.
- » The legislation in Serbia related to chemicals and, especially restrictions and SVHC substance management (listing the SVHC substances on the Candidate List), should be fully harmonised with EU legislation shortly after its adoption in the EU. Timing is very important for the restriction as the Serbian market should be a market for products that are banned in the EU. In addition, the management of SVHCs should be a priority for chemical legislation, bearing in mind the hazardous properties of these substances.

- » The competent authorities should analyse products placed on the market and intensify the enforcement. A monitoring programme for restricted products should be adopted and implemented, which would contribute to the protection of the health of our children and all people in Serbia.
- » The use of PVC should be limited in public procurement policies as it is a problematic plastic which requires the use of phthalates as plasticisers.
- » The possibility of developing a database in Serbia to which companies will submit data on substances of very high concern (SVHCs) in their articles which are placed on the Serbian market in order for them to be safely recycled needs to be considered. This is key to a better circular economy and essential in order to make the The Green Agenda for the Western Balkans work.
- » **Companies**
Phthalates and other SVHCs in everyday products should be replaced by safe alternatives as soon as possible. Safer alternatives should be chosen on the basis of appropriate information related to the hazardous properties of alternative substances.

- » Companies at every stage of the supply chain should pass information related to SVHCs in compliance with the Serbian Law on Chemicals. Information on SVHCs must be disseminated along the supply chain and ultimately made available to the public and consumers. Explicitly, all companies selling articles that contain more than 1% of SVHCs in Serbia should comply with the national legislation and inform consumers on request about the presence of SVHCs in products.
 - » Companies should proactively test products and sign agreements with suppliers guaranteeing that the chemical composition of products complies with the legal requirements for chemicals.
 - » Companies should be made more aware of the new restrictions imposed by the European and Serbian legislation so that they are correctly implemented.
 - » It is also time to rethink the replacement of PVC in as many products as possible, in particular those used by more sensitive groups, such as children or pregnant women.
- What can consumers do?**
- » Avoid articles made of plastic polymers, especially of PVC, since they can contain softeners such as phthalates. You will recognise this material according to the recycling sign, with the number 3.
 - » Scan products you want to buy in advance with the Scan4Chem app and send an SVHC request to the seller or manufacturer of the item. Scan as many products as possible with the Scan4Chem app to show companies that consumers want safe products!
 - » Ventilate rooms regularly! Phthalates present in toys and other household products can end up in house dust.
 - » Look out for products with eco-labels.

Annex I

Restrictions on phthalates in Serbia and the European Union



Restrictions on phthalates in Serbia – Extract from Part 1, Annex 1 of the RULEBOOK ON RESTRICTIONS AND BANS ON THE PRODUCTION, PLACEMENT ON THE MARKET, AND USE OF CHEMICALS (Official Gazette of RS, no. 90/13, 25/15, 2/16, 44/2017, 36/18 and 9/2020)

No. of ban and restriction	Name of the substance, group of substances, or mixtures, CAS number and EC number	Restrictions and bans
51.	<p>Phthalates</p> <p>a. Bis(2-ethylhexyl) phthalate, DEHP CAS no. 117-81-7, EC br. 204-211-0</p> <p>b. Dibutyl phthalate, DBP CAS no. 84-74-2, EC br. 201-557-4</p> <p>c. Benzyl butyl phthalate BBP CAS no. 85-68-7, EC br. 201-622-7</p>	<ol style="list-style-type: none"> 1. Use of these substances or mixtures containing them in toys and baby care products is banned in concentrations exceeding 0.1% (m/m) of plasticised material. 2. Placement on the market of toys and baby care products containing more than 0.1% (m/m) of these phthalates is banned. 3. A baby care product means any product that eases sleep, relaxes, maintains hygiene, or is used for the feeding or breastfeeding of infants.
52.	<p>Phthalates</p> <p>a. Di-isononyl phthalate, DINP CAS no. 28553-12-0 and 68515-48-0, EC no. 249-079-5 and 271-090-9</p> <p>b. Di-isodecyl phthalate, DIDP CAS no. 26761-40-0 and 68515-49-1, EC no. 247-977-1 and 271-091-4</p> <p>c. Di-n-octyl phthalate, DNOP CAS no. 117-84-0, EC no. 204-214-7</p>	<ol style="list-style-type: none"> 1. The use of these substances or mixtures containing them in toys and baby care products that children can put in their mouth in concentrations exceeding 0.1% (m/m) of plasticised material is banned. 2. Placement on the market of toys and baby care products containing more than 0.1% (m/m) of these phthalates is banned. 3. A baby care product means any product that eases sleep, relaxes, maintains hygiene, or is used for the feeding or breastfeeding of infants.



Restriction of phthalates in the European Union – Extract from ANNEX XVII TO REACH Regulation on the Registration, Evaluation, Authorisation, and restriction of CHEMicals – Restrictions on the manufacture, placing on the market, and use of certain dangerous substances, mixtures, and articles

No. of ban and restriction	Name of the substance, group of substances, or mixtures, CAS number and EC number	Restrictions and bans
51.	Bis(2-ethylhexyl) phthalate (DEHP) CAS No.: 117-81-7 EC No.: 204-211-0 Dibutyl phthalate (DBP) CAS No.: 84-74-2 EC No.: 201-557-4 Benzyl butyl phthalate (BBP) CAS No.: 85-68-7 EC No.: 201-622-7 Diisobutyl phthalate (DIBP) CAS No.: 84-69-5 EC No.: 201-553-2	<ol style="list-style-type: none"> 1. Shall not be used as substances or in mixtures, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0.1% by weight of the plasticised material, in toys and childcare articles. 2. Shall not be placed on the market in toys or childcare articles, individually or in any combination of the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0.1% by weight of the plasticised material. In addition, DIBP shall not be placed on the market after 7 July 2020 in toys or childcare articles, individually or in any combination with the first three phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0.1% by weight of the plasticised material. 3. Shall not be placed on the market after 7 July 2020 in articles, individually or in any combination of the phthalates listed in column 1 of this entry, in a concentration equal to or greater than 0.1% by weight of the plasticised material in the article. 4. Paragraph 3 shall not apply to: <ol style="list-style-type: none"> a. articles exclusively for industrial or agricultural use, or for use exclusively in the open air, provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin; b. aircraft, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those aircraft, where those articles are essential for the safety and airworthiness of the aircraft; c. motor vehicles within the scope of Directive 2007/46/EC, placed on the market before 7 January 2024, or articles, whenever placed on the market, for use exclusively in the maintenance or repair of those vehicles, where the vehicles cannot function as intended without those articles; d. articles placed on the market before 7 July 2020; e. measuring devices for laboratory use, or parts thereof; f. materials and articles intended to come into contact with food within the scope of Regulation (EC) No 1935/2004 or Commission Regulation (EU) No 10/2011 (*1); g. medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC, or parts thereof; h. electrical and electronic equipment within the scope of Directive 2011/65/EU; i. the immediate packaging of medicinal products within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC or Directive 2001/83/EC; j. toys and childcare articles covered by paragraphs 1 or 2.

		<p>5. For the purposes of paragraphs 1, 2, 3 and 4(a),</p> <p>a. ‘plasticised material’ means any of the following homogeneous materials:</p> <ul style="list-style-type: none"> — polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes, — any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings, — surface coatings, non-slip coatings, finishes, decals, printed designs, — adhesives, sealants, paints, and inks. <p>b. ‘prolonged contact with human skin’ means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.</p> <p>c. ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children, or sucking on the part of children.</p> <p>6. For the purposes of paragraph 4(b), ‘aircraft’ means one of the following:</p> <p>a. a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 or with a design approval issued under the national regulations of a contracting State of the International Civil Aviation Organisation (ICAO), or for which a certificate of airworthiness has been issued by an ICAO contracting State under Annex 8 to the Convention on International Civil Aviation, signed on December 7, 1944, in Chicago;</p> <p>b. a military aircraft.</p>
1a2	<p>Phthalates</p> <p>a. Di-isononyl phthalate, DINP CAS no. 28553-12-0 and 68515-48-0, EC no. 249-079-5 and 271-090-9</p> <p>b. Di-isodecyl phthalate, DIDP CAS no. 26761-40-0 and 68515-49-1, EC no. 247-977-1 and 271-091-4</p> <p>c. Di-n-octyl phthalate, DNOP CAS no. 117-84-0, EC no. 204-214-7</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0.1% by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.</p> <p>2. Such toys and childcare articles containing these phthalates in a concentration greater than 0.1% by weight of the plasticised material shall not be placed on the market.</p> <p>3. (Regulation (EU) No 326/2015: paragraph 3 is deleted.)</p> <p>4. For the purpose of this entry ‘childcare article’ shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children, or sucking on the part of children.</p>

Annex II

List of the phthalates on the Candidate List of substances of very high concern for Authorisation

(published in accordance with Article 59(10) of the REACH Regulation)

	Substance name and acronym	EC number	CAS number
1	Di-(2-ethylhexyl) phthalate (synonym: bis(2-ethylhexyl) phthalate) DEHP	204-211-0	117-81-7
2	Benzyl butyl phthalate BBP	201-622-7	85-68-7
3	Dibutyl phthalate DBP	201-557-4	84-74-2
4	Diisobutyl phthalate DIBP	201-553-2	84-69-5
5	Di-n-pentyl phthalate DPP	205-017-9	131-18-0
6	Diisopentyl phthalate DIPP	210-088-4	605-50-5
7	n-pentyl-isopentyl phthalate NIIPP	-	776297-69-9
8	Di-(2-methoxyethyl) phthalate (synonym: bis(2-ethoxyethyl) phthalate) DMEP	204-212-6	117-82-8
9	Di-n-hexyl phthalate DNHP	201-559-5	84-75-3
10	Dicyclohexyl phthalate DCHP	201-545-9	84-61-7
11	Diisohexyl phthalate	276-090-2	71850-09-4

Annex III

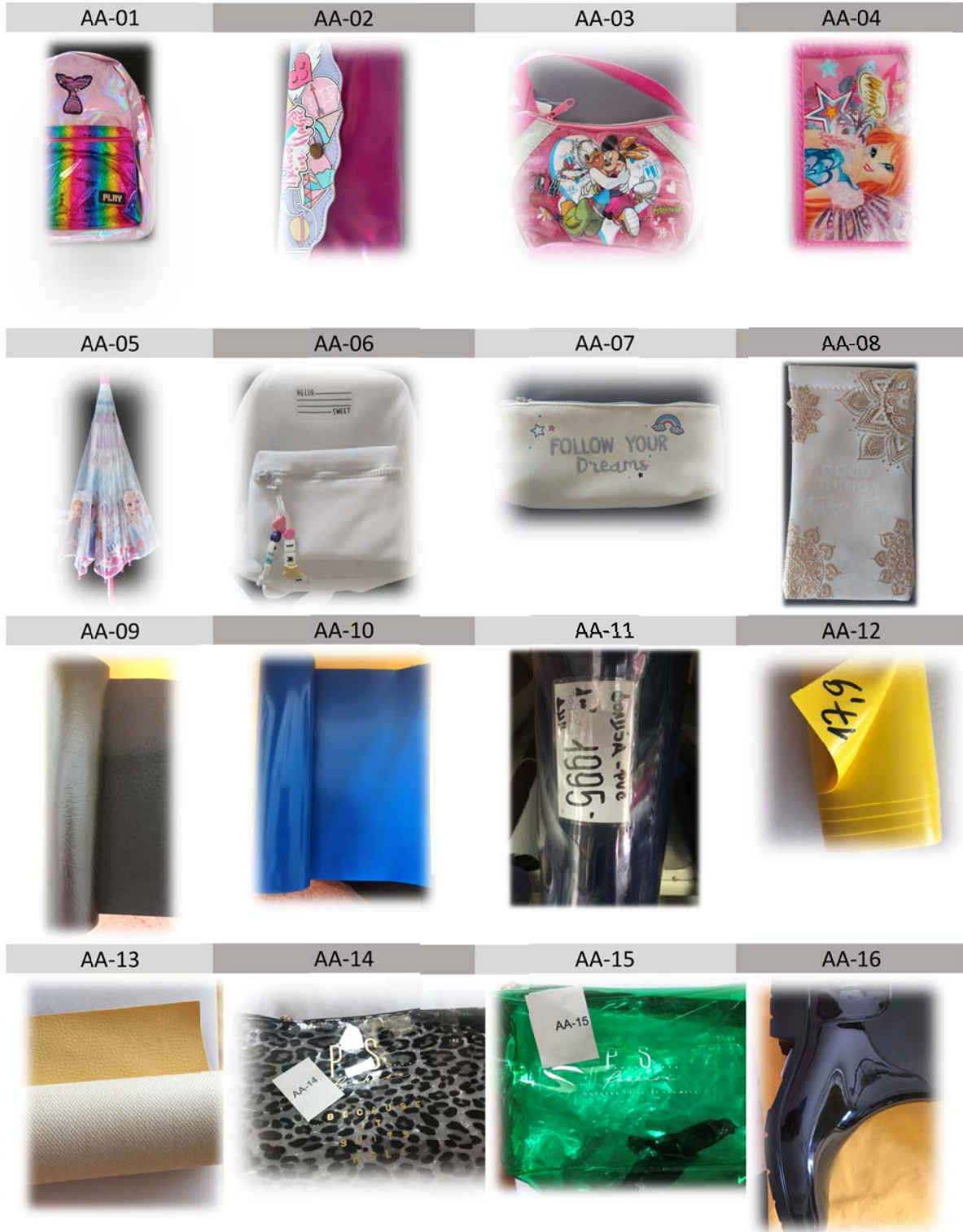
Table with phthalate content in tested samples
















SAMPLE ID	Name and description of the product	Lab results (phthalates %)				'Right to information' companies answer
		BBP	DBP	DEHP	DIBP	
AA-01	School bag	<0.01	<0.01	17.88	<0.01	No
AA-02	Pencil box	<0.01	<0.01	0.03	<0.01	No
AA-03	Children's (girl's) bag	<0.01	0.03	0.16+/-0.03	<0.01	No
AA-04	Children's wallet	<0.01	<0.01	0.03	<0.01	No
AA-05	Children's umbrella	<0.01	<0.01	<0.01	<0.01	No
AA-06	Children's white backpack	<0.01	<0.01	11.08	<0.01	No
AA-07	Woman's toilet bag	<0.01	<0.01	0.03	<0.01	No
AA-08	Case for glasses	<0.01	<0.01	0.03	<0.01	No
AA-09	Artificial leather	<0.01	<0.01	<0.01	<0.01	No
AA-10	PVC fabric tarpaulin	<0.01	<0.01	<0.01	<0.01	No
AA-11	PVC transparent foil	<0.01	<0.01	0.02	<0.01	No
AA-12	PVC fabric tarpaulin	<0.01	0.71	<0.01	<0.01	No
AA-13	Artificial leather	<0.01	<0.01	18.15	<0.01	No
AA-14	Women's toilet bag	<0.01	<0.01	<0.01	<0.01	No
AA-15	Women's toilet bag	<0.01	<0.01	13.86	<0.01	No
AA-16	Black gum boots	<0.01	<0.01	<0.01	<0.01	No
AA-17	Self-adhesive PVC foil	<0.01	<0.01	5.38	<0.01	No
AA-18	Children's (girl's) bag PVC	<0.01	<0.01	<0.01	<0.01	No

SOFT plastic, HARSH truth

AA-19	Food placemat PVC (white/ black)	<0.01	<0.01	0.04	<0.01	No
AA-20	Inflatable drink holder for swimming pool	<0.01	<0.01	<0.01	<0.01	No
AA-21	Children's boots	<0.01	<0.01	<0.01	<0.01	No
AA-22	PVC shower hose	<0.01	<0.01	<0.01	<0.01	No
AA-23	Flexible waste pipe	<0.01	<0.01	<0.01	<0.01	No
AA-24	PVC transparent foil soft	<0.01	<0.01	<0.01	<0.01	No
AA-25	PVC car mat	<0.01	0.26	2.89	5.07	No
AA-26	Inflammable ring for swimming	<0.01	<0.01	<0.01	<0.01	No
AA-27	PVC gloves with talk	<0.01	<0.01	0.01	<0.01	No
AA-28	Children's slippers PVC	<0.01	<0.01	0.18+/-0.04	<0.01	No
AA-29	Boy's T-Shirt	<0.01	<0.01	<0.01	<0.01	No
AA-30	Girl's raincoat	<0.01	<0.01	<0.01	<0.01	Yes
AA-31	Gymnastic mats	<0.01	<0.01	0.01	<0.01	Yes
AA-32	Pocket spiral notebook	<0.01	<0.01	<0.01	<0.01	Yes
AA-33	Girl's raincoat	<0.01	<0.01	10.33	<0.01	No
AA-34	Children's gum boots	<0.01	0.01	<0.01	0.02	No
AA-35	Women's T-shirt	<0.01	<0.01	<0.01	<0.01	No
AA-36	Non-slip bath mat	<0.01	0.05	0.02	<0.01	No

Pictures of tested articles



AA-17	AA-18	AA-19	AA-20
			
AA-21	AA-22	AA-23	AA-24
			
AA-25	AA-26	AA-27	AA-28
			
AA-29	AA-30	AA-31	AA-32
			

AA-33



AA-34



AA-35



AA-36



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