GreenFacts — Facts on Health and the Environment

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on consumer products
on emerging and newly identified health risks
on health and environmental risks

Phthalates in school supplies

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GreenFacts

Level 2 - Details on Phthalates in school supplies

The answers to these questions are a faithful summary of the scientific opinion produced in 2008 by the Scientific Committee on Health and Environmental Risks (SCHER):
"Opinion on phthalates in school supplies"

The full publication is available at: https://copublications.greenfacts.org/en/phthalates-school-supplies/
and at: http://ec.europa.eu/health/opinions/en/phthalates-school-supplies/

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1. Introduction: why is there a concern over phthalates in school supplies?

The Danish EPA found a variety of phthalates in school supplies.
Source: scol22, sxc.hu

Phthalates are a group of chemical compounds widely used as additives in a range of plastics and other materials that are found in many consumer products. They make plastics, such as PVC, soft and flexible. They are not chemically bound to plastics, so they can be released from consumer products into the environment and may result in human exposure. There is public concern about phthalates because of their widespread use, including in products for children, and their potential effects on human health.

Many different phthalates exist with different properties, uses, and health effects. Several of them have been assessed within an EU program on Risk Assessment for new and existing chemical substances. In 2005, the European Union adopted a directive that bans some phthalates in toys (products designed or clearly intended for use in play by children) and childcare articles (products intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children):

- In all toys and childcare products DEHP (di-(2-ethylhexyl) phthalate), DBP (dibutyl phthalate), and BBP (benzyl butyl phthalate) are banned.
- In those toys and childcare products that children could place into their mouths, Di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP), and di-n-octyl phthalate (DNOP) are banned. "Placing in the mouth" means that the article or parts of an article can actually be brought to the mouth and kept in the mouth by children so that it can be sucked and chewed.

The Danish Environmental Protection Agency (EPA) has recently analysed and detected the presence of phthalates in school supplies such as school bags, play bags, pencil cases and erasers. After doing tests to measure the possible exposure of children through normal use of those products, the Danish EPA concluded that, in general, there were no risks associated with the chemicals contained in the school supplies when these are used normally.

However, the study points out that some of the erasers that were made of PVC contained DEHP as a plasticizer, and children who have the habit of sucking or biting pieces off erasers may be exposed to harmful levels of DEHP. The study also stresses that it analysed only a few products, and that there might be other articles with higher phthalate contents. There could also be other sources of these chemicals in the child's environment that would contribute to the total exposure.

For two other phthalates, DIBP and DINP, the Danish EPA concluded that exposure was significantly below the level that would pose a risk.

Also, there have been claims that certain consumer products contain phthalates other than those banned, even though we still know little about their risks. Although such claims are unconfirmed so far, it appears plausible that such phthalates may be used in order to avoid a conflict with the ban.

2. How was the Danish study on phthalates in school supplies conducted?

2.1 What was the methodology followed?

A number of items, including erasers, were analysed for chemical content.
Source: Allen Pope

The Danish Environmental Protection Agency (Danish EPA) tested school supplies for the presence of phthalates as part of a wider programme that investigates exposure and possible risk of chemicals in consumer products and articles. After a market survey, a number of school bags, toy bags, pencil cases and erasers were bought and analysed.

A chemical analysis was carried out to detect the presence of various substances in these articles. More specifically:

- chlorine content was investigated in order to identify the products containing PVC (polyvinyl chloride).
- some product samples were tested to see what types of polymer they contained.
- X-Ray analysis was used to assess the presence of chlorine, bromine, tin, sulphur and nickel.
- the potential release of volatile organic compounds (VOCs) was evaluated.
- some product samples were analysed for specific metals, colouring agents, antioxidants and perfluorinated compounds
- to what extent chemicals pass from the sample to artificial sweat and saliva was studied.

Of all products, 46 including 26 erasers, were tested in more detail to find out how much they contained of each chemical. Nine of the erasers contained phthalates. Three of them contained 22-44% of DEHP and six contained 32-70% DINP. The study also found DIBP and DBP in some of the products, but did not measure the total content of these phthalates. It studied the extent to which chemicals from 14 products pass into artificial sweat and saliva, but none of these products were erasers. The results showed that DIBP and DEHP were released by 11 and 5 products respectively.

The major exposure route to phthalates from the products investigated in the Danish study is by licking, chewing and swallowing small pieces of the item. The SCHER agrees with the conclusion that erasers may be the only relevant source for phthalates from the selection of school supplies investigated, and the other products tested do not present a health risk for children. The only potential source of concern in the study was exposure to DEHP from erasers through sucking and chewing, and this is the main focus of the present opinion.

2.2 What are the weaknesses of the Danish study?

In general, the way the Danish study was designed and the report derived from this study contain several weaknesses, which makes it difficult to come to conclusions based on the results. The report from the Danish study is confusing as not all details required for an evaluation are included. Furthermore, the information it gives on quality assurance of the analyses is limited and sometimes contradicting.

The SCHER agrees that the presence of phthalates in school supplies other than erasers is of low concern since contact with the skin – which is limited – may be the only reasonable way for children to be exposed and that only small amounts of phthalate go through the skin. However, erasers that contain phthalates may be of concern because they can leach DEHP and DINP when children put them in their mouths. But it was not possible for the

SCHER to make a proper risk assessment of this potential exposure because of deficiencies in the report. Notably:

How much DEHP pass into artificial saliva was only studied from one eraser in a sample that had been cut into small pieces. This gives a much larger surface area of contact between the eraser and the artificial saliva and results in excessive leaching of the plasticizer. It was calculated that the results could be six times higher than the true values. Proper analyses on the release of DEHP into artificial sweat give much lower values and are further evidence that the results of the Danish study are overestimates.

- When the artificial saliva was analysed to measure the amount of DEHP that had leached into it, it still contained small pieces of eraser that had not been removed and this could overestimate DEHP release even more.

- The uncertainty of the results is reported to be 50%, which indicates that the chemical analyses are of poor quality.

- The Danish study should have used artificial gastric juice to measure a potential release of phthalate from swallowed bits of eraser.

In summary, the SCHER considers that due to the many weaknesses in this study and its reporting, the figures given for the amounts of DEHP and DINP leached cannot be used as a basis to assess the potential health risk of phthalates released from erasers.

3. To what extent can children be exposed to phthalates through erasers?

The exposure of a child to DEHP and DINP from erasers by licking and chewing depends on:

- how much phthalates from the eraser passes into the saliva;
- how long the child sucks or chews on the eraser and in what way;
- how much of the eraser is swallowed as small particles;
- to what extent the phthalates from these particles passes into gastric juice;
- to what extent phthalates are absorbed in the body from saliva and the gastrointestinal tract.

Exposure of children to phthalates from erasers is from chewing or licking. Source: GreenFacts

According to the Danish study a child is exposed to 120 µg of DEHP per square cm of eraser which is in contact with its saliva for an hour (120 µg/cm^2/h), but this is likely to be a six-fold overestimate. This rate of transfer from eraser to saliva is comparable to the highest DEHP values measured in a US study and ten times higher than the results for DINP releases in two European studies. Therefore, in this risk assessment, the figure of 120 µg/cm^2/h is considered a worst-case scenario. It is also assumed that 100% of the phthalate in the saliva or in swallowed particles passes into the body.

The Danish report also assumed that a child sucks on a piece of eraser for one hour per day, which the SCHER considered a reasonable worst case given that most children hardly ever put an eraser into their mouths.

In the Danish report, the exposure through ingestion of small solid particles after chewing was calculated for 8, 50 and 100 mg of particles per day. However, practical experiences show that such bitten-off pieces of eraser are not easily swallowed, and the SCHER considers that 8 mg of particles per day is the only realistic value.

Another big unknown, which represents the largest uncertainty factor in this assessment, is how frequently children bite and swallow bits of erasers.

With these assumptions, the total exposure to DEHP from 1 cm^2 of an eraser containing 44% DEHP may be 0.1 mg or up to 4 mg per child per day depending on whether the child merely licks the eraser or if particles are bitten off and swallowed. When combining all worst-case scenarios, exposure to DEHP from chewing erasers could reach up to 4.1 mg per child per day, which is equivalent to 0.2 mg/kg body weight per day for a 6 year old child who weighs 20 kg. This is four times the tolerable daily intake (TDI) of 0.05 mg/kg body weight per day. The margin of safety compared to the lowest level of DEHP at which no adverse effect were observed in animals (NOAEL) is 25, when the generally accepted margin of safety is 100 times.

However, licking on erasers and swallowing bits of them is a short-lived habit and children are unlikely to swallow large amounts of eraser in this way. The exposure time is short and phthalates are rapidly transformed and eliminated from the body. Comparing such worst case short term exposures with the TDI, which is meant for regular, lifetime exposures, is not really appropriate here. Moreover, the assessment of exposure by swallowing particles relies on a single exploratory experiment, which needs to be repeated to confirm the findings. Only very few children in the groups where DEHP intake was determined from urine samples (biomonitoring) exceeded the TDI.

4. To what extent are people exposed to phthalates?

The EU-Risk Assessment Reports (RAR) on various phthalates have made a detailed assessment of exposure based on known concentrations in food, the environment and materials, and models that predict what proportion of the substance is taken up by the body. For DNOP, however, no such assessment report is available and information on use patterns, occurrence, and human exposures is lacking.

The diet, particularly fatty food, is responsible for most of the DEHP exposure in adults. Source: Steve Woods

More recent studies assess human exposures to phthalates by measuring the biological breakdown products in urine, since this method gives more precise estimates. One such study on children in Germany showed that exposure was higher in boys than in girls, and children aged 6-7 years were significantly more exposed than children in the age group 13-14 years.

Overall, our knowledge of how the body takes in phthalates and how it transforms, metabolises and eliminates them is limited. In addition, the extent to which age influences these processes has not been sufficiently evaluated. Still, the average exposure of children is known to be approximately twice that of adults. Different lifestyle factors, eating behaviours, and the ingestion of dust from indoor surfaces may also play a role. A recent study from Germany comparing concentrations in the food and in the urine of 5-8 year old boys indicated that diet was responsible for about 50 % of their exposure to DEHP, so other important sources must exist. For adults, DEHP exposure is mainly due to diet, particularly fatty foods.

While DEHP was the phthalate most commonly used in consumer products in the 1990s, it has since been increasingly replaced by DIDP because of health concerns. Between 1999 and 2004, the proportion of DEHP in total phthalates use decreased from 42% to 22% and the proportions of DINP and DIDP increased from 35% to 58%. The change in use has been reflected in a change in exposure to these two phthalates. A study in Germany on 20-29 year olds showed continuous decrease in DEHP exposure from 1996 until 2003 and a corresponding increase in DINP exposure.

A US study calculated the daily intake of DINP in children of different ages, based on estimates of how long children put products containing DINP into their mouth and of how much would pass into the body. The average estimate was 0.0057 mg/child/day for children aged between 3 and 12 months, but there were very large variations, with 5% of children expected to take in 0.0943 mg/child/day or more. The values for children at 13-26 months were considerably lower with a mean of less than 0.001 mg/child/per day. At present, there is a lack of direct measurements of the breakdown products of DINP or other phthalates in the urine of children that would allow a more precise assessment of exposure.

In conclusion, the exposure data based on urine samples indicate that average exposures are well below the tolerable daily intake (TDI) for DEHP, but it may approach or even exceed the TDI in some highly-exposed groups of population, notably people exposed through medical procedures such as kidney dialysis. For the other phthalates studied, calculated exposures are below the TDIs except for DBP. A significant portion of the population may be exposed to doses of DBP above the TDI and efforts to further reduce exposures are needed.

Measured urinary concentrations for different phthalates [see Annex 2, p. 10]

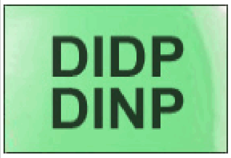
Overview of the main phthalates and their applications [see Annex 1, p. 9]

5. What daily exposure levels to phthalates are considered safe?

See also our publication on Di-butyl phthalate [see https://www.greenfacts.org/en/dbp-dibutyl-phthalate/index.htm]

Current understanding about the effects of exposure to a specific phthalate on human health is mainly based on findings from animal studies.

Above certain exposure levels different phthalates do cause harmful effects in animals. The harmful effects of a given phthalate that occur at the lowest levels of exposure are referred to as critical toxic effects.



See also our publication on Di-isodecyl & Di-isononyl phthalates [see https://www.greenfacts.org/en/dinp-didp/index.htm]

Phthalates banned across the EU in all toys and childcare articles, and in cosmetics:

- DEHP (Di-(2-ethylhexyl) phthalate)
  The critical toxic effects of DEHP that appear at the lowest exposure level relate to reproduction. The no-observed adverse effect level (NOAEL) for reproductive and developmental effects is 4.8 mg/kg body weight per day body weight per day, and the tolerable daily intake (TDI) is 0.05 mg/kg body weight per day. Exposure to DEHP at the doses observed in humans does not represent a relevant risk for the development of cancer.
- BBP (Benzylbutyl phthalate)
  Studies on rats show a NOAEL for BBP of 100 mg/kg body weight per day for effects on reproductive organs. The NOAEL for developmental effects was 20 mg/kg body weight per day in a study and of 50 mg/kg body weight per day in another report. The TDI for BBP is 0.5 mg/kg body weight per day.
- DBP, sometimes written DNBP (Di-n-butyl phthalate)
  The toxicity of DBP targets the male reproductive system, with a NOAEL of 50 mg/kg body weight per day. A study on rats showed that feeding DBP to mothers in late pregnancy and during lactation affected the development of both male

and female offspring. A NOAEL could not be established, but a TDI of 0.01 mg/kg body weight per day was derived using a high safety factor.

Phthalates banned in toys and childcare products that children could put into their mouths:

- DINP (Di-isononyl phthalate)
  DINP is a mixture of compounds with different chemical structures, but with similar properties. The main toxicological effects for DINP are changes in the liver, with a NOAEL of 15 mg/kg body weight per day, and a TDI of 0.15 mg/kg body weight per day. For adverse effects on reproduction, the NOAEL varies between 500 mg/kg body weight per day and 622 mg/kg body weight per day.
- DIDP (Di-isodecyl phthalate)
  DIDP and DINP are very similar, both in structure and properties. There is no indication that DIDP has any effect on the reproductive organs. Overall, a NOAEL for effects on the liver of 15 mg/kg body weight per day derived from a study on dogs can be considered for humans. Although no TDI is available, exposures below 0.15 mg/kg body weight per day are of low concern as this figure is 100 smaller than the NOAEL, which is a good margin of safety.
- DNOP (Di-n-octylphthalate)
  The results of toxicological studies show that DNOP is very unlikely to cause adverse reproductive and developmental effects. However, it can have an effect on the activity of the liver and damage the thyroid. No TDI is available for DNOP.

Not yet evaluated in an EU Risk Assessment Report:

- DIBP (Di-isobutyl phthalate)
  The effects of DIBP on development and reproduction are similar to those observed for DBP and DEHP. However, there is no information on how these effects depend on the dose given. Further studies are thus needed to characterise the effects of DIBP on reproduction and derive a NOAEL. A TDI has not been defined.

Overview table of critical toxic effects and Tolerable Daily Intakes (TDI)

Phthalate	Critical Toxic Effect on	Tolerable daily intake (in mg per kg body weight per day)	EU ban
DEHP	Reproduction	0.05	Banned in all toys and childcare articles, and in cosmetics
BBP	Reproduction and development	0.5	
DBP		0.01	
DINP	Liver	0.15	Banned in toys and childcare products that children could put into their mouths
DIDP			
DNOP	Liver and thyroid	No TDI available	
DIBP	Reproduction and development		-

6. Conclusions

Phthalates in tested school supplies do not contribute significantly to total exposure of children. Source: Ivaylo Georgiev

The Scientific Committee on Health and Environmental Risks (SCHER) concludes that the phthalates present in the school supplies tested by the Danish Environment Protection Agency do not significantly contribute to the total amount of phthalates taken in by children.

Based on urine samples from people of different ages, it is concluded that total exposures to individual phthalates in the general population are below the tolerable daily intakes (TDI), except in the case of DBP for which efforts to further reduce exposures are needed. Exposure to DEHP may exceed the TDI in some specific population groups, namely people exposed through medical procedures such as kidney dialysis (see the SCENHIR opinion on "the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk" available here).

Moreover, based on the single exploratory experiment available that assessed the rate at which DEHP in an eraser passed into artificial saliva, the SCHER estimated that biting off pieces from an eraser and swallowing these particles could lead to an exposure that exceeds the TDI by a factor of 4, but this is still 25 times lower than the No Observed Adverse Effect Level (NOAEL) for DEHP that has been established from long-term experiments. Since swallowing particles bitten off an eraser represents a short-time habit of children or even a one-time event, it is unlikely that such exposure leads to health consequences.

In any case, the SCHER stresses the great uncertainty of the evaluation carried out by the Danish EPA and proposes further research as outlined in its opinion on Organic Chemicals in Toys (read this 2007 SCHER opinion [see http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_056.pdf]).

Overview table of critical toxic effects and Tolerable Daily Intakes (TDI)

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DBP		0.01	
DINP	Liver	0.15	Banned in toys and childcare products that children could put into their mouths
DIDP			
DNOP	Liver and thyroid	No TDI available	
DIBP	Reproduction and development		-

Annex

Annex 1:

Some phthalates and their applications

Acronym	Full name	Examples of applications (past or present)	EU ban
DEHP	Di-Ethyl-Hexyl-Phthalate	Perfumes, flexible PVC products (shower curtains, garden hoses, diapers, food containers, plastic film for food packaging, bloodbags, catheters, gloves, and other medical equipments such as tubes for fluids, etc.)	Banned in all toys and childcare articles, and in cosmetics
BBP	Butyl-Benzyl-Phthalate	Perfumes, hair sprays, adhesives and glues, automotive products, vinyl floor coverings	
DBP	Dibutyl-Phthalate	Plastics such as PVC, adhesives, printing inks, sealants, grouting agents used in construction, additive to perfumes, deodorants, hair sprays, nail polish, and insecticides	
DINP	Di-Isononyl Phthalate	Mostly in PVC as a plasticizer; Remaining in rubbers, inks, adhesives and sealants, paints and lacquers.	Banned in toys and childcare products that children could put into their mouths
DIDP	Di-Isodecyl-Phthalate	Mostly in PVC as a plasticizer; Remaining in rubbers, anti-corrosion paints, anti-fouling paints, sealing compounds, and textile inks.	
DNOP	Di-n-Octyl-Phthalate	Medical tubing and blood storage bags, wire and cables, carpetback coating, floor tile, and adhesives, cosmetics and pesticides.	
DIBP	Di-isobutyl phthalate	Nitro cellulose plastic, nail polish, explosive material, lacquer Similar application and properties as DBP: used as a substitute, e.g. in PVC, paints, printing inks and adhesives	-

Source: GreenFacts

Annex 2:

Table 1: Urinary concentrations of mono-(2-ethyl-5-hydroxyhexyl)phthalate (MEHHP), mono-isobutyl phthalate (MIBP), and mono-benzyl phthalate (MBeP) to assess daily intakes of di(2-ethylhexyl)phthalate (DEHP), mono-butyl phthalate (MmBP), di-n-butyl phthalate (DNBP), di-isobutyl phthalate (DIBP), and benzylbutyl phthalate (BBP).

	Metabolite concentration (µg/g creatinine)			Phthalate intake (µg/kg b.w.)			Year of sampling	Reference
Age, number	**Median**	**95th Percentile**	**Max**	**Median**	**95th Percentile**	**Max**		
DEHP (EFSA TDI of 50 µg/kg bw/day)								
USA								
6-11 y, n: 392	34.2	211	-	3.8	24	-	2001/02	NCEH 2005
>20 y, n: 1638	15.0	134	-	1.7	15	-		
6-9 y; n: 90	43.8 [a]	-	-	5.0	-	-	2004/05	Wolff et al. 2007
6-10 y; n: 35	76.4	592	1101	8.7	67	125	2004	Teitelbaum et al. 2008
Germany								
3-14 y, n: 254	39.9	170	1990	4.5	19	227	2001/02	Becker et al. 2004
2-7 y; n: 36	55.8	107	129	6.4	12	15	2003	Koch et al. 2004b
20-59 y; n: 19	28.1	64	103	3.2	5.7	12		
DNBP (EFSA TDI of 10 µg/kg bw/day)								
USA								
6-11 y, n = 392	35.1	146	-	1.3	5.3	-	2001/02	NCEH 2005
>20 y, n: 1638	15.4	71.6	-	0.6	2.6	-		
6-9 y; n: 90	44.1[a]	-	-		-	-	2004/05	Wolff et al. 2007
6-10 y; n: 35	52.6	165.1	661	1.9	6.0	24.0	2004	Teitelbaum et al. 2008
Germany								
2-14 y, n = 239	136	491	2102	4.9	17.8	76	2001/02	Koch et al 2007
DIBP (no TDI allocated)								
USA								
6-11 y, n: 392	5.2	24	-	0.2	0.9	-	2001/02	NCEH 2005
>20 y, n: 1638	2.2	11	-	0.1	0.4	-		
6-9 y; n: 90	11.1	-	-	0.4	-	-	2004/05	Wolff et al. 2007
6-10 y; n: 35	15.6	50.9	158	0.7	1.8	5.7	2004	Teitelbaum et al. 2008
BBP (EFSA TDI of 500 µg/kg bw/day)								
USA								
6-11 y, n = 392	37.2	195	-	1.2	6.5	-	2001/02	NCEH 2005
>20 y, n: 1638	11.8	64.9	-	0.4	2.2	-		
6-9 y; n: 90	28.7[a]	-	-	1.0	-	-	2004/05	Wolff et al. 2007
6-10 y; n: 35	36.6	288	824	1.2	9.6	27.5	2004	Teitelbaum et al. 2008
Germany								
2-14 y, n = 239	13.2	82.7	567	0.4	2.8	18.9	2001/02	Koch et al. 2007

*geometric mean

Source: SCHER Opinion on phthalates in school supplies (2008), [see http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_106.pdf]
Section 3.4.1 "Exposure assessment", pages 11-12.