Context - Phthalates are additives that are widely used in plastics to make them soft and flexible.

To protect children from potential health effects, certain phthalates are no longer used in toys and childcare articles. However, some school supplies – such as erasers, bags or pencil cases – were found to contain these phthalates.

Can regularly chewing on such articles cause harmful health effects?

An assessment by the European Commission Scientific Committee on Health and Environmental Risks (SCHER)

1. Introduction: why is there a concern over phthalates in school supplies?.................2
2. How was the Danish study on phthalates in school supplies conducted?.....................2
3. To what extent can children be exposed to phthalates through erasers?....................3
4. To what extent are people exposed to phthalates? ..........................................3
5. What daily exposure levels to phthalates are considered safe?....................................4
6. Conclusions..........................................4

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"


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- Each question is answered in Level 1 with a short summary.
- These answers are developed in more detail in Level 2.
- Level 3 consists of the Source document, the internationally recognised scientific opinion which is faithfully summarised in Level 2 and further in Level 1.

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

Phthalates are a group of chemical compounds used in the production of plastics such as PVC to make them softer and more flexible. When present in consumer products, phthalates can be released because they are not chemically bound to the plastics. This may lead to human exposure, which has raised public concern. Many different phthalates exist with different properties, uses, and health effects. Because of their potential effects on human health, the European Union has banned the use of six specific phthalates in products for children. Notably, DEHP, DBP and BBP have been banned in all toys and childcare articles, and DINP, DIDP and DNOP have been banned only in those articles that children could suck and chew on.

In a recent study, the Danish Environmental Protection Agency (EPA) found a variety of phthalates in school supplies – including in erasers – and concluded that, in general, the tested supplies do not pose any health risks when used normally.

However, the Danish study warned that some of the tested erasers which contained DEHP may present health risks, when children regularly suck and chew on them.

Also, some manufacturers might now use other types of phthalates which have not been banned in consumer products.

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

2.1 In the framework of the study carried out by the Danish Environmental Protection Agency (Danish EPA), a number of school bags, toy bags, pencil cases, and erasers available in shops were analysed to see the type and the amount of chemical substances they contained and how much would be released if children bit or licked them.

The school supplies items considered most relevant were erasers due to their small size that makes them likely candidates for repeated chewing. Of the 26 erasers analysed in detail, three contained DEHP and six DINP. Some of the other school supplies also contained some DIBP or DBP. In general, the tested school supplies were considered not to present a health risk for children, except erasers containing DEHP.

The European Commission Scientific Committee on Health and Environmental Risks (SCHER) agreed with the Danish EPA that, among all school supplies tested, the only ones that may be of concern are erasers as children could repeatedly suck or chew on them.

2.2 However, the SCHER considers that a proper risk assessment of the potential exposure to phthalates from erasers cannot be made based on the Danish study because of the various shortcomings in the way it was designed and conclusions were drawn. Indeed, measurements of how much phthalate passes into artificial saliva were made only on one eraser and in ways that probably resulted in great overestimates of the true values. Moreover, the method used had other weaknesses and the results are very uncertain.
3. To what extent can children be exposed to phthalates through erasers?

The exposure of children to DEHP and DINP from erasers by licking and chewing depends on how long they keep the eraser in their mouths, how many small bits of eraser they swallow, how much of the phthalates passes into saliva or into gastric juice, and how the substance is taken up by the body through digestion.

The study from the Danish EPA gives estimates of how much passes into saliva if a child puts an eraser in its mouth during an hour per day, a situation that is considered reasonable worst-case scenarios by the European Commission Scientific Committee on Health and Environmental Risks (SCHER). It is assumed that all the phthalates in saliva or gastric juice passes into the body through digestion. The hardest factor to estimate is how much of the eraser is swallowed after chewing bits off it; and this is the largest source of uncertainty in the assessment.

With these assumptions, the combined worst-case scenarios result in exposures four times higher than the tolerable daily intake (TDI) for DEHP. 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. Therefore, comparing such worst-case short-term exposures with the TDI, which is meant for regular, lifetime exposures, is not really appropriate here.

4. To what extent are people exposed to phthalates?

The EU-Risk Assessment Reports (RAR) on various phthalates estimated the likely exposure from food, materials and the environment.

Although little is known about how DEHP and other phthalates are taken in, transformed and eliminated by the body and how exposure varies for different age groups, 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 by children may play a role. The diet, particularly fatty food, is responsible for most of the DEHP exposure in adults while it only accounts for half of the DEHP that children take in, which suggests that, for children, other important sources exist.

While DEHP was the phthalate most commonly used in consumer products in the 1990s, since then it has been increasingly replaced by DIDP because of health concerns. The change in use has been reflected in a change in exposure to these two phthalates. The levels of exposures of the general population to DEHP – estimated based on urine samples – are on average well below the tolerable daily intake (TDI). However, some groups of the population, notably people exposed through medical procedures such as kidney dialysis, might be exposed to considerably higher levels which approach or even exceed the TDI.

In the case of the other phthalates assessed by the EU Risk Assessment reports, calculated exposures are below the tolerable level 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.
Overview of the main phthalates and their applications [see Annex 1, p. 6]

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

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 the different phthalates can cause harmful effects in animals. For a given phthalate, the harmful effects that occur at the lowest levels of exposure are referred to as critical toxic effects.

These critical toxic effects include effects on reproduction (DEHP, BBP, DBP, DIBP), on development (BBP, DBP, DIBP), on the liver (DINP, DIDP, DNOP), and on the thyroid (DNOP).

Based on available experimental findings a tolerable daily intake (TDI) has been established for humans for the different phthalates, except for DNOP and DIBP. The TDI is an estimate of the amount that can be taken in by humans on a daily basis over a lifetime without appreciable health risk.

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

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

6. Conclusions

The European Commission Scientific Committee on Health and Environmental Risks (SCHER) concludes that the phthalates found 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 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 tolerable intake in some specific population groups, namely people exposed through medical procedures such as kidney dialysis.

Even in the case when children bite off pieces from erasers and swallow them, the SCHER considers that it is unlikely that this exposure leads to health consequences.
In any case, the Scientific Committee stresses the great uncertainty of the evaluation carried out by the Danish EPA and recommends further research.
Annex 1:

Some phthalates and their applications

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full name</th>
<th>Examples of applications (past or present)</th>
<th>EU ban</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEHP</td>
<td>Di-Ethyl-Hexyl-Phthalate</td>
<td>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.)</td>
<td>Banned in all toys and childcare articles, and in cosmetics</td>
</tr>
<tr>
<td>BBP</td>
<td>Butyl-Benzyl-Phthalate</td>
<td>Perfumes, hair sprays, adhesives and glues, automotive products, vinyl floor coverings</td>
<td></td>
</tr>
<tr>
<td>DBP</td>
<td>Dibutyl-Phthalate</td>
<td>Plastics such as PVC, adhesives, printing inks, sealants, grouting agents used in construction, additive to perfumes, deodorants, hair sprays, nail polish, and insecticides</td>
<td></td>
</tr>
<tr>
<td>DINP</td>
<td>Di-isononyl Phthalate</td>
<td>Mostly in PVC as a plasticizer; Remaining in rubbers, inks, adhesives and sealants, paints and lacquers.</td>
<td>Banned in toys and childcare products that children could put into their mouths</td>
</tr>
<tr>
<td>DIDP</td>
<td>Di-Isodecyl-Phthalate</td>
<td>Mostly in PVC as a plasticizer; Remaining in rubbers, anti-corrosion paints, anti-fouling paints, sealing compounds, and textile inks.</td>
<td></td>
</tr>
<tr>
<td>DNOP</td>
<td>Di-n-Octyl-Phthalate</td>
<td>Medical tubing and blood storage bags, wire and cables, carpetback coating, floor tile, and adhesives, cosmetics and pesticides.</td>
<td></td>
</tr>
<tr>
<td>DIBP</td>
<td>Di-isobutyl phthalate</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>

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