The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate (DINP) in Children's Products

Executive Summary

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U.S. Consumer Product Safety Commission
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Overview

1. The U.S. Consumer Product Safety Commission (CPSC) is investigating the potential health risks to children under 3 years of age from teethers, rattles, and toys made from polyvinyl chloride (PVC) containing a chemical DINP (diisononyl phthalate) used to make the PVC softer.

2. Based on the work the staff has conducted and other scientific studies currently available, the staff concludes that few, if any, children are at risk from liver or other organ toxicity from the release of DINP from these products. This is because the amount they might ingest does not reach a level that would be harmful.

3. The staff believes that uncertainties remain relating to estimations of risk, including the risk of cancer, and that additional studies are needed. The staff recommends CPSC undertake the following additional work:

* Convene a Chronic Hazard Advisory Panel of independent scientists to study issues related to the chronic toxicity and risk, including the risk of cancer, associated with exposure to DINP in children's PVC products.

* Conduct an extensive exposure study to obtain a broader range of data from which to better define the amount of time children mouth products that could contain phthalates.

* Continue work to develop a laboratory test method that better estimates the amount of phthalate released when products are mouthed by children.

* Conduct additional testing of products intended for children under 3 years of age that contain DINP.

Description of Work to Date

CPSC staff has evaluated the potential health risks to children under 3 years of age from teethers, rattles, and toys made from polyvinyl chloride (PVC) containing DINP.

This evaluation included laboratory testing to simulate the mouthing by young children of products that contain DINP and other phthalates. These tests provided information on the amount and type of phthalate released. CPSC staff also conducted tests using adult volunteers to compare the amount of DINP found in laboratory tests to the amount released when adults sucked or gently chewed on a piece of product.

CPSC staff analyzed the literature and other available information on the health effects of the DINP found in the children's products mentioned above. Staff also evaluated available information on the amount of time children would mouth products such as toys, teethers, and rattles.

The information obtained from testing and analysis of the literature was used to estimate the potential hazard to children. Staff found the magnitude of the risk is directly related to the amount of DINP released from mouthing and the amount of time children mouth the products.

CPSC Study Findings

A number of important findings resulted from the Commission's study. These include the following:

Phthalates Found in Children's Products

* Based on products tested, DINP is the predominant phthalate used to soften PVC that is contained in some children's products sold in the United States. CPSC staff tested 35 children's PVC products that contained phthalates: 31 contained DINP, two (a pacifier and a baby bottle nipple) contained diisooctyl phthalate (DIOP), one (a soother) contained dinonyl phthalate (DnNP), and one (a child's purse) contained di(2-ethylhexyl) phthalate (DEHP). With pacifiers and baby bottle nipples, only one manufacturer was found to have some models that contained a phthalate. These models have been removed from the market. All other known pacifiers and baby bottle nipples are made from latex or silicone and therefore do not contain phthalates.

Release of DINP from Products

* CPSC laboratory testing of children's products likely to be mouthed by children under 3 years of age showed wide variability in the amount of DINP released. The amount of DINP used to soften the products also varied widely. Importantly, however, the staff found no relationship between the amount of DINP used in the product and the amount released when tested in the laboratory.

Measuring Release of DINP

* CPSC staff found that, based on information currently available, the method used to manufacture the product (e.g., injection or rotational molding or sheeting) does not correlate with the amount of DINP released. The staff also found that there is currently no laboratory test method

available to estimate adequately the amount of DINP released during laboratory testing that correlates with the amount released when products are mouthed by humans. Work on developing such a method is proceeding at CPSC and in Europe.

* CPSC staff used 10 adult human volunteers to mouth a piece of a children's toy that contained DINP to determine the release of DINP. The amount of DINP released was higher than the amount released during CPSC laboratory simulation testing. The results indicated that there was a 39.5 fold higher level released during the human subjects testing. Accordingly, the staff applied this factor to increase the DINP release rates measured in the laboratory for the 31 products found to contain DINP.

Data on Children's Exposure

* CPSC staff found that the data available to estimate actual times that children put items that may contain phthalates in their mouths is very limited. The best data comes from a study released by the Dutch Consensus Panel in September 1998. The staff has relied on this data to estimate exposure to children for calculating risk. All previously published estimates of exposure have been based on professional judgment, but not on actual time measurements. The Dutch study found wide variability in the amount of time children spend mouthing. The study also found that children under 1 year of age spend considerably more time mouthing than do children 1 to 3 years of age. Since the Dutch Study was relatively small, CPSC staff recommends a larger observational exposure study in children ranging in age from 3 months to 3 years.

Acceptable Daily Intake

* Animal studies show that DINP causes chronic toxic effects to the liver and other organs. In order to determine the level at which humans are at risk CPSC staff calculated an acceptable daily intake (ADI) for humans. The ADI is a level that is not expected to cause harmful health effects in humans. Using data from the animal studies, staff calculated an acceptable daily intake (ADI) for humans to be 150 micrograms per kilogram of body weight per day. This value is derived by taking the highest level of exposure that did not result in an adverse health effect to animals and applying a 100-fold safety factor to account for possible differences between animals and humans and for differences in the sensitivity among individuals.

Estimated Exposure of Children

* CPSC staff estimated the exposure to DINP from children's teethers, rattles, and toys. This information is provided in the table below. The data show that none of the daily intake estimates exceed the 150 micrograms per kilogram per day acceptable daily intake (ADI). No estimate of risk is provided for pacifiers or baby bottle nipples because only one manufacturer was found to have models that contained a phthalate (DIOP). This manufacturer has stopped using phthalates.

Estimated Exposure of Children to DINP in Teethers, Rattles, and Toys

Children's Age	Estimated Daily Intake of DINP (μg/kg/day)			
	Geometric Mean	Confidence* Interval (CI)	95th Percentile	Confidence* Interval (CI)
3-12 Months	5.7	2.5-12.9	94.3	50.1-225.6
13-26 Months	0.7	0.3-1.6	7.6	4.4-16.2

*The Confidence Intervals shown in the table are a measure of uncertainty in the estimates of the Geometric Mean and 95th Percentile.

Possible Further Risk from DINP

* One animal study also found that DINP caused an increased incidence of liver tumors (carcinomas and adenomas) in rats and mice. There is uncertainty about the actual mechanism by which compounds such as DINP contribute to cancer in animals and whether this mechanism applies to humans. In addition, there is controversy over what model is appropriate to use to calculate any risk. CPSC staff recommends that a Chronic Hazard Advisory Panel of independent scientists evaluate the available scientific data and advise the Commission on this issue.

Conclusions

The CPSC staff concludes that based on the best available information about the amount of DINP released from the products tested by the staff and relying on the exposure information from the Dutch study, few, if any, children are at risk of liver or other organ toxicity from mouthing teethers, rattles, and other PVC toys that contain DINP. However, there are a number of significant uncertainties in this assessment including the cancer risk, and further work is necessary to gather better data on which to base the health risk assessment.

Recommended Future Work

CPSC staff recommends the Commission undertake additional work to address the uncertainties that can affect the estimate of the risk to children. The additional work includes:

* Convening a Chronic Hazard Advisory Panel of independent scientists to study issues related to the chronic toxicity and risk, including the risk of cancer, associated with exposure to DINP in children's PVC products.

* Conducting an extensive exposure study to obtain a broader range of data from which to better define the amount of time children mouth products that could contain phthalates.

* Continuing work to develop a laboratory test method that better estimates the amount of phthalate released when products are mouthed by children.

* Conducting additional testing of products intended for children under 3 years of age that contain DINP.