



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

SEP 18 2002

SEP 18 2002

VOTE SHEET

DATE: SEP 18 2002

TO: The Commission
 Todd A. Stevenson, Secretary

FROM: Melissa V. Hampshire, Acting General Counsel
 Stephen Lemberg, Assistant General Counsel
 Lowell F. Martin, Attorney, GCAL (ext. 2217)

SUBJECT: Petition Requesting Ban of Use of PVC in Products Intended for Children Five Years of Age and Under (HP 99-1)

VOTE SHEET

The attached staff briefing package recommends that the Commission deny petition HP 99-1 requesting a ban of polyvinyl chloride (PVC) in all toys and other products intended for children five years of age and under and decline to issue a national advisory warning of health risks associated with soft plastic vinyl toys. The petition based these requests on the toxicity of diisononyl phthalate (DINP), a plasticizer used in PVC, and the toxicity and presence of lead and cadmium in PVC. The staff bases its recommendation on the conclusion that there is no demonstrated health risk posed by PVC toys or other products intended for children five years of age and under.

Please indicate your vote on the following options.

I. DENY PETITION HP 99-1 AND ISSUE THE DENIAL LETTER AS DRAFTED.

 (Signature)

 (Date)

II. DENY PETITION HP 99-1 AND ISSUE THE DENIAL LETTER WITH REVISIONS.
 (PLEASE SPECIFY.)

 (Signature)

 (Date)

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Initial rh Date 9/18/02

Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: <http://www.cpsc.gov>

Page 1 of 2

CPSC 5 (01) Cleared

9-18-02
 No Mfrs/PrvtLbrs
 Products Identified
 Excepted by [Signature]

III. GRANT PETITION 99-1. STAFF WILL PREPARE A DRAFT NOTICE OF PROPOSED RULEMAKING FOR COMMISSION CONSIDERATION.

(Signature)

(Date)

IV. DECLINE TO ISSUE A NATIONAL ADVISORY ON THE HEALTH RISKS THAT HAVE BEEN ASSOCIATED WITH SOFT PLASTIC VINYL TOYS.

(Signature)

(Date)

V. ISSUE A NATIONAL ADVISORY ON THE HEALTH RISKS THAT HAVE BEEN ASSOCIATED WITH SOFT PLASTIC VINYL TOYS.

(Signature)

(Date)

VI. TAKE OTHER ACTION. (PLEASE SPECIFY.)

(Signature)

(Date)

Attachment

Response to Petition HP 99-1
Request to Ban PVC in Toys and Other Products Intended for Children Five Years
of Age and Under

Marilyn L. Wind, Ph.D.
Project Manager for PVC Petition
Directorate for Health Sciences
U.S. Consumer Product Safety Commission
August 2002

NOTE: This document has not been
reviewed or accepted by the Commission.
Initial MLW Date 9/18/02

~~CONFIDENTIAL~~ ~~Clear~~
9-18-02
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Products Identified
X Exempted by Paul

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Executive Summary

Phthalates are chemicals used to make polyvinyl chloride (PVC) flexible. Until the mid-1980's di-(2-ethylhexyl) phthalate (DEHP) was the primary phthalate used in children's toys and products made from PVC. As a result of a voluntary agreement with the Toy Manufacturers of America (now the Toy Industry Association, Inc.), which was later incorporated into the Standard Consumer Safety Specification on Toy Safety (ASTM F-963), the industry stopped using DEHP in pacifiers, rattles, and teethingers. DEHP was replaced with another phthalate, diisononyl phthalate (DINP).

In 1997 and 1998, chronic toxicity studies on DINP were completed by industry. Staff from the U.S. Consumer Product Safety Commission (CPSC) completed a preliminary risk assessment on DINP in March 1998 and a more in-depth risk assessment was made public in December 1998. At that time, staff concluded, "based on the best available information about the amount of DINP released from products tested by the staff and relying on the mouthing duration data from the Dutch study, few, if any, children are at risk of liver or other organ toxicity from mouthing teethingers, rattles and other PVC toys that contain DINP." Staff indicated that there were a number of uncertainties in the analysis and recommended the Commission: a) convene a Chronic Hazard Advisory Panel (CHAP) to evaluate whether there are chronic hazards associated with exposure to DINP and what if any risk is posed; b) conduct an extensive observation study of children's mouthing behavior; c) develop a better laboratory method to measure the migration of DINP; and d) test additional products intended for children under 3 years of age. As a result of the uncertainties, a voluntary agreement was reached with industry to not use DINP in teethingers, rattles, and pacifiers.

In November 1998, the Commission received a submission (HP 99-1) from the National Environmental Trust and eleven other organizations requesting that the Commission:

- immediately ban PVC in all toys and other products intended for children five years of age and under and
- issue a national advisory on the health risks that have been associated with soft plastic vinyl toys to inform parents and consumers about the risks associated with PVC toys currently in stores and homes.

The primary reason given for the requests was the risk posed by children being exposed to DINP. They also referred to lead and cadmium in PVC and the hazard posed by these two chemicals. The request for a ban was docketed as petition HP 99-1. The request for a national health advisory was not docketed because it would not require rulemaking. In June 2001, Greenpeace petitioned CPSC to broaden the scope of the prior petition to include all household products made from PVC. This request was denied in July 2001 because it did not meet statutory or Commission regulatory requirements for docketing as a petition for rulemaking.

The Commission voted to convene a CHAP in December 1998. The CHAP met three times in 2000 and submitted its report to the Commission on June 15, 2001. The CHAP

concluded that "there may be a DINP risk for any young children who routinely mouth DINP-plasticized toys for 75 minutes/day or more. For the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury." They also concluded that at the levels to which children were exposed there was no carcinogenic, reproductive, or developmental risk.

CPSC conducted a behavioral observation study in 2000 and early 2001 in order to better quantify phthalate exposure to children. One hundred sixty-nine (169) children between the ages of 3 months and 36 months were observed by trained observers for a total of four hours, two hours on each of two days. The mean daily mouthing time of soft plastic toys for children 12-24 months of age (the age group with the highest mouthing time) was 1.9 (1.2-2.6) minutes/day.

CPSC staff measured the level of migration of DINP from 41 children's products purchased from retail stores. The method used to measure the migration was the TNO Nutrition and Food Research Institute method as modified by the European Joint Research Center. Migration rates from DINP-containing articles ranged from 1.0 to 11.1 $\mu\text{g}/10\text{cm}^2/\text{min}$.

The CHAP members indicated that they had concern for children who mouth toys more than 75 minutes a day. Based upon the observation study, staff concludes it is very unlikely that children will mouth soft plastic toys for more than 75 minutes a day. As part of a new risk assessment, staff conducted a worst case analysis. Since pacifiers have the highest mouthing times of any toys, even though they do not currently contain dialkyl phthalates, staff assumed that pacifiers contained DINP and that DINP migrated out of the pacifiers at a rate seen in soft plastic toys. With this worst case analysis, even the 99th percentile exposure would not exceed the acceptable daily intake (ADI). Since children mouth other products even less than they mouth toys and dermal penetration is expected to be minimal, staff does not believe they would pose a risk to children five years of age and under.

Staff recommends that the Commission deny the petition and decline to issue the requested national health advisory. The staff concurs with the CHAP conclusion that exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury for the majority of children. The new data from the behavioral observation study not only confirm this conclusion, but demonstrate that children are exposed to DINP at lower levels than the CHAP assumed when it reached its conclusion. Also, since children mouth other products even less than they mouth toys and dermal exposure is expected to be negligible, there would be no justification for taking action against other products intended for children five years old and younger. Further, staff issued a report in November 1997 on lead and cadmium in children's PVC products and concluded, "...children would not be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner." No data were presented by the petitioners that would alter the Commission staff conclusion or that would justify a ban of PVC products based upon lead and/or cadmium exposure from these products.



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

Memorandum

Date: August 13, 2002

TO : The Commission

THROUGH: Todd A. Stevenson, Secretary *TAS*
 Melissa V. Hampshire, Acting General Counsel *MVA*
 Patricia M. Semple, Executive Director

FROM : Jacqueline Elder, Acting Assistant Executive Director
 Office of Hazard Identification and Reduction
 Marilyn L. Wind, Ph.D., Deputy Associate Executive Director *MW*
 Directorate for Health Sciences

SUBJECT : Response to Petition HP 99-1

The purpose of this package is to respond to the petition and request to issue a national health advisory from the National Environmental Trust and eleven other organizations (HP 99-1). The petition requests that the U.S. Consumer Product Safety Commission (CPSC) ban the use of polyvinyl chloride (PVC) in all toys and other products intended for children 5 years of age and under. The petitioner also requested a national advisory warning of the health risks associated with PVC toys. The petitioners give as the primary reason for their requests the toxicity of diisononyl phthalate (DINP), a plasticizer in PVC and the toxicity and presence of lead and cadmium in PVC. This package presents findings from a Chronic Hazard Advisory Panel (CHAP) convened by the Commission, the results of an extensive observation study of children's mouthing behavior, new migration data, and an updated risk assessment to support the staff recommendation on the petition and request for a national health advisory.

Background

Phthalates are chemicals used to make polyvinyl chloride (PVC) flexible. In the early 1980's the primary plasticizer used in pacifiers, baby bottle nipples, and other PVC toys was di-(2-ethylhexyl) phthalate (DEHP). In 1983, the Commission completed a risk assessment on DEHP. The Commission published a Federal Register Notice on December 22, 1983 indicating its concern that the use of DEHP in children's products might result in a substantial exposure of children to a substance that causes cancer in animals. The Commission convened a CHAP¹ pursuant to the Consumer Product Safety Act (CPSA)² on January 31, 1985. In September 1985, the CHAP presented its report to the Commission and based upon rodent carcinogenicity studies, concluded that there could be an added risk to children from oral exposure to children's

¹ A CHAP is a panel of scientific experts that reviews scientific data and other relevant information regarding any potential risks of cancer, birth defects, or gene mutations from the presence of a chemical in consumer products.

² Consumer Product Safety Act, as amended, 15 U.S.C. 2051-2084.

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products containing DEHP of roughly 20-100 deaths per year. The CHAP also recommended further research to develop more accurate measures of exposure.

The Commission reached a voluntary agreement with the Toy Manufacturers of America (now called The Toy Industry Association, Inc.) that was later incorporated into ASTM F-963, Standard Consumer Safety Specification on Toy Safety. The standard states, "Pacifiers, rattles and teethers shall not intentionally contain di-(2-ethylhexyl) phthalate (also known as dioctyl phthalate). To prevent trace amounts of DEHP from affecting analysis, up to 3% of total solid content will be accepted in the result, when tested in accordance with Practice D 3421." This agreement effectively eliminated DEHP from pacifiers, rattles, teethers, as well as from many other children's toys. The phthalate that was substituted for DEHP was diisononyl phthalate (DINP).

Chronic toxicity studies on DINP were completed by industry in 1997 and 1998. Commission staff completed a risk assessment that was made public in December 1998. In that risk assessment, the staff concluded, "based on the best available information about the amount of DINP released from the products tested by the staff and relying on the mouthing duration data 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." Staff did not assess the risk of cancer from mouthing teethers, rattles, or other PVC toys that contain DINP at that time. Staff also indicated that there were a number of uncertainties in the analysis and recommended that the Commission:

- convene a Chronic Hazard Advisory Panel (CHAP) 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 a more extensive exposure study of the amount of time children mouth products that may contain phthalates,
- continue work to develop a laboratory test method that more accurately estimates the amount of phthalate released when products are mouthed by children, and
- conduct additional testing of products intended for children under 3 years of age that contain DINP.

On December 2, 1998, the Commission issued a press release announcing the release of this risk assessment. In addition, the press release announced a voluntary agreement with toy manufacturers to remove DINP from rattles and teethers and another phthalate, dioctyl phthalate, from pacifiers and baby bottle nipples. The press release also noted that a number of large retail chains had agreed not to sell rattles, teethers, pacifiers, or baby bottle nipples that contained phthalates.

Petition

Prior to the release of the 1998 risk assessment, the Commission received requests (TAB A) from the National Environmental Trust and eleven other organizations asking the Commission:

- a) to immediately ban PVC in all toys and other products intended for children five years of age and under, and
- b) to issue a national advisory on the health risks that have been associated with soft plastic vinyl toys to inform parents and consumers about the risks associated with PVC toys currently in stores and homes.

The primary reason given for the requests was that DINP was used in PVC as a softener and it posed a hazard to children. They also referred to lead and cadmium in PVC and the hazard posed by these two chemicals. The request for a ban was docketed as petition HP 99-1. The request for a national health advisory was not docketed because it would not require rulemaking. In June 2001, Greenpeace requested that the CPSC broaden the scope of the prior petition to include all household products made from PVC. In July 2001, that request was denied because it did not satisfy the requirements of the Federal Hazardous Substances Act (FHSA) or the Commission's regulations for docketing as a petition for rulemaking (TAB B).

Commission staff generally responds to a petition based upon the information present in the petition and off-the-shelf information. However, the Commission already had a project on DINP and the staff had recommended that the Commission convene a CHAP and initiate a behavioral observation study. Since Commission work was ongoing in this area, a decision was made to not respond to the petition until after the CHAP issued its report and the behavioral observation study was completed. This was because the information being developed was likely to have some bearing on the staff response and recommendations to the Commission on the petition.

DINP CHAP

Based upon the recommendation of the staff, the Commission voted on December 17, 1998 to convene a CHAP on DINP. The mission of this panel was to determine whether DINP is a carcinogen, mutagen, or teratogen, or poses some other chronic hazard and, if feasible, estimate the probable harm to human health that could result from exposure to DINP.

Formation of the CHAP and its activities were conducted in accordance with sections 28 and 31 of the CPSA, 15 U.S.C. 2077, 2080.

The President of the National Academy of Sciences selected candidate members for the CHAP. The Commission selected seven panel members based upon their scientific expertise, after screening them for conflicts of interest. One of the scientists selected declined; a replacement

was selected who subsequently was not allowed to participate by his employer. The final selection was made on May 25, 2000. A list of CHAP members can be found at TAB C.

On April 26, 2000 the Commission published a Federal Register Notice (FR 65(81): 24458) announcing the first meeting of the CHAP. On May 30, 2000 the Commission published another Federal Register Notice (FR 65(104): 34446) inviting public comment at the second CHAP meeting and requesting information in a number of areas.

The CHAP met three times in open session: May 10-11, 2000; June 20-22, 2000; and September 12-13, 2000. Transcripts of all the meetings are available from the CPSC's Office of the Secretary. At the first CHAP meeting, the panel members chose Dr. Kenneth Bogen as the Chairman and Dr. Kim Boekelheide as the Vice-Chairman. In addition, the Commission staff made presentations on the toxicity of DINP, the existing studies on children's mouthing behavior, the new study that the Commission was beginning on children's mouthing behavior, the migration of DINP from toys, and other national and international activities on DINP. The CHAP then discussed the format of the report and what further information it wanted. Prior to the June meeting, a Federal Register notice was published listing information the CHAP wanted and soliciting public comment.

At the June 2000 CHAP meeting, public interest groups, industry scientists, and academics made presentations. The presenters at that meeting are listed in TAB D. The CHAP spent the remainder of this meeting and the September meeting addressing specific issues and drafting and reviewing parts of the report.

DINP CHAP Report

The final CHAP Report was submitted to the Commission on June 15, 2001. The Executive Summary is at TAB E. The entire report can be found on the web at <http://www.cpsc.gov/LIBRARY/FOIA/Foia01/os/dinp.pdf>

The CHAP dealt with complex scientific issues and analyses. The members considered the available data and used their scientific expertise and judgment to reach their conclusions. They indicated that they reached these conclusions despite some data gaps and uncertainties. The CHAP concluded:

- The most significant exposures to DINP are likely to occur from the use of consumer items, particularly PVC toys routinely mouthed by children, that consist of flexible plastic softened using DINP.
- An acceptable daily intake (ADI) of 0.120 mg/kg-d was calculated based upon a Benchmark Dose (BD₀₅) estimate of 12 mg/kg-d and a 100-fold uncertainty/adjustment factor. Spongiosis hepatitis, a degenerative lesion of the liver, was identified as the most sensitive endpoint in animals and it is this effect upon which the benchmark dose is based.
- For the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury. They further concluded

that there may be a DINP risk for any young children who routinely mouth DINP-plasticized toys for 75 minutes/day or more.

- Since the doses to which it is expected that pregnant women would be exposed are so much lower than those expected to be without effect in animal assays, the risk to reproductive and developmental processes in humans due to DINP exposure is extremely low or non-existent.
- Although dermal uptake of DINP may occur through prolonged contact of DINP-containing products with skin or mouth, data on the prevalence of DINP in consumer products are not available and there is a fundamental uncertainty concerning the magnitude of dermal DINP uptake. Therefore, estimation of potential dermal exposure to humans remains speculative.
- Although DINP is clearly carcinogenic in rodents inducing liver tumors in rats and mice of both sexes, kidney tumors in male rats and mononuclear cell leukemia in male and female rats, the human risk from cancer induced by DINP is negligible or non-existent. This conclusion was based upon the following:
 - DINP is non-genotoxic and causes liver cancer by a mechanism known as peroxisome proliferation.
 - The peroxisome proliferator-activated receptor α (PPAR α) mediated mechanism of hepatocarcinogenesis is pronounced in rodents, but believed not readily induced in humans, especially at the doses resulting from current use of consumer products. The human risk of liver carcinogenicity was, therefore, seen as negligible or non-existent.
 - The male rat kidney tumors were viewed as rat specific since they met the criteria for supporting an $\alpha_2\mu$ -globulin mechanism of action, a mechanism accepted as unique to male rats. They were not used to predict human risk.
 - The mononuclear cell leukemia in Fischer 344 rats was viewed of questionable significance and was not used in human risk prediction.

The CHAP indicated that there were uncertainties which fell into two different areas, those related to exposure and those related to determining the hazard.

Uncertainties relating to exposure were as follows:

- Lack of knowledge about what portion of toys contain DINP
- Lack of knowledge about what other consumer products contain DINP
- Lack of knowledge about how much DINP migrates out of toys and other consumer products
- Uncertainties about how much time each day a child spends mouthing toys and other objects containing DINP
- Lack of knowledge about how much, if any, DINP would be dermally absorbed

Uncertainties relating to hazard were as follows:

- The degree to which spongiosis hepatitis, a degenerative liver lesion, in rodents is relevant to humans
- How to extrapolate an effect from a lifetime exposure in rodents to a two-to-three year exposure in young children
- Lack of knowledge of effects of chemical exposures early in life; there are no toxicological data for exposures corresponding to infancy and toddler years
- Lack of knowledge of effects in non-rodents; there are no chronic studies in non-rodent animals
- Lack of knowledge of PPAR α expression and related responses in the young; there are no data in human infants and children and scant data in non-human species
- Lack of knowledge on mechanisms by which PPAR α induces rodent liver tumors

Behavioral Observation Study

Both the CPSC staff and the CHAP members agreed that one area posing a great deal of uncertainty was that of exposure to DINP. The Commission staff, therefore, conducted a behavioral observation study to determine how much time young children actually spend mouthing objects and what types of objects they mouth. For a detailed description of the study and how the data were analyzed, see the report, "A Mouthing Observation Study of Children Under 6 Years," at TAB F, the report, "Mouthing Times For Children From the Observational Data," at TAB G, the report, "Mouthing Times and DINP Risk for Children Over Three years of age," at TAB H and "Oral Intake of DINP Among Young Children," at TAB K.

The study was conducted in two phases. In Phase I, parents or legal guardians of children ranging in age from 3 to 81 months were instructed to observe their child for four, 15-minute non-consecutive sessions and to record both the objects mouthed and the duration of the mouthing behavior. A total of 491 children were selected by random digit dialing in the Houston and Chicago areas and observed as described above. Data on demographics and on the children's waking and sleeping habits were also collected.

In Phase II, trained professional observers recorded the mouthing behaviors of 169 children between 3 and 36 months of age. One hundred nine (109) of the Phase I children between ages 3 and 36 months participated in Phase II. An additional 60 children participated in Phase II who had not participated in Phase I. Phase II consisted of two, 3-hour sessions (6 hours total), 4 hours of which included timed observations. While observing the children at their homes or day care providers, the observers recorded a description of every object that the subject child touched to or put into his mouth, as well as the length of time that object was in contact with the child's mouth.

The mouthing time data provided by the parents or legal guardians in Phase I, did not appear to be as high quality as the observers' data for either children 36 months and younger or for children over 36 months of age. A preliminary analysis of these data showed that in many cases, parents recorded a total of more than 15 minutes of mouthing time during a 15-minute period. While these data discrepancies were not a serious problem for the 109 children aged 36 months

or younger who also participated in the Phase II study, they are problematic for the older children because these data are the only mouthing data available for this age group.

As a result, it is not possible at this time to provide a quantitative DINP risk assessment for children over 36 months of age. However, the data collected for this study, and the data available in published literature, indicate that mouthing behavior declines as children age. Based on these published data and even without specific data in this present study, it seems reasonable to conclude that children over 36 months are very likely to experience lower DINP intake than younger children.

Data from Phase II on the average daily mouthing time of children are summarized in Table 1.

Table 1: Average Mouthing Behavior in minutes/day (95% confidence limits) of Children 3 to 36 Months of Age

Objects Mouthed	3-12 months	12-24 months	24-36 months
All objects except pacifiers	70.1 (60.6-79.8)	47.4 (38.9-57.1)	37 (27-48.5)
Soft plastic items ³	4.4 (3.0-6.1)	3.8 (2.8-4.9)	4.2 (2.5-6.1)
All soft plastic toys	1.3 (0.7-2.0)	1.9 (1.2-2.6)	0.8 (0.3-1.6)

Note: Upper age endpoint for each age range not included in the group except for 24-36 months. Children exactly 12 months are in the 12-24 month group.

While Table 1 summarizes the average daily mouthing time of children for a variety of objects, Table 2 specifically summarizes the 95th and 99th percentiles values of daily mouthing times for soft plastic toys. These data represent the most highly exposed children (i.e. the children who mouth plastic toys the longest), as compared to the mean or average mouthing times.

Table 2: Estimated Daily Mouthing Times for Soft Plastic Toys in minutes/day (95% confidence limits) of Children 3 to 36 Months of Age

Age	Mean	95 th Percentile	99 th Percentile
3-12 months	1.3 (0.7-2.0)	7.1 (3.9-11.0)	10.5 (5.8-13.7)
12-24 months	1.9 (1.2-2.6)	8.8 (5.6-11.7)	12.6 (9.0-16.0)
24-36 months	0.8 (0.3-1.6)	3.3 (1.4-16.3)	12.1 (2.0-21.0)

Note: Upper age endpoint for each age range not included in the group except for 24-36 months. Children exactly 12 months are in the 12-24 month group.

The estimates in Table 2 are lower than those used in previous CPSC and other analyses of risk to children from mouthing DINP-containing products, but they represent a more detailed characterization of objects mouthed than did earlier analyses. In the previous studies, no distinction was made between plastic toys and non-plastic toys. In one study, results were only reported for pacifiers and non-pacifiers. Non-pacifiers included teething rings, plastic toys, fingers and a wide range of objects. Groot et al., the study used in the European Union's and the CPSC's 1998 DINP risk assessment, found the mean mouthing duration for all toys among 6-12 month

³The category, Soft Plastic Items, includes all soft plastic items the child mouthed, not just toys.

olds was 27.9 minutes. The geometric mean mouthing time for all toys was 12 minutes for 3-12 month olds and 2 minutes for the older children. (See TABs F, G, H, K, and L)

In this new study, the mean mouthing time for all soft plastic toys is 1.9 minutes/day and the 99th percentile mouthing time is 12.6 minutes/day for 12-24 month old children, the group with the highest exposure. Since the mouthing behavior of children directly correlates with exposure to DINP and exposure is important in calculating risk, it is important to use the most accurate figure available. Since the study conducted by CPSC employed professional observers and recorded detailed descriptions of every item placed in a child's mouth, we believe that it provides the best exposure data available for use in the DINP risk assessment.

Phthalate Migration and Toy Screening

To accurately predict risk, the amount of phthalate that migrates out of toys and to which children could be exposed, must be known. Phthalate migration from toys has been measured by a variety of different methods that have given a broad range of results (TAB I). The methods used for measuring the migration of phthalates from toys included shaking, ultrasound, tumbling, and impaction. A tumbling method, known as the "head over heels" or TNO method, was developed at the TNO Nutrition and Food Research Institute, The Netherlands, and has been modified by the European Joint Research Centre (JRC). This method has been tested in two international interlaboratory studies and compares favorably with *in vivo* studies⁴. See TAB J for the Executive Summary from the 2001 interlaboratory validation study report. The TNO method, as modified by JRC, is the one that the CPSC laboratory used to determine the amount of phthalate that migrates out of selected PVC toys currently on the market.

In order to determine the level of DINP migration from toys containing DINP and to determine which toys contained DINP, CPSC staff purchased 41 children's plastic products from retail stores. Toys were selected based upon their labeling which indicated that they could be mouthed, sucked or chewed. Since a number of the toys contained more than one type of plastic, 133 specimens from the toys were analyzed. Of these, 51 of the specimens contained PVC, 30 contained DINP, and three contained DEHP. See TAB K for a complete discussion of the methodology used and for a detailed description of the results.

Of the 30 DINP-containing articles, 6 were not tested for DINP migration since they were either too small or were a shape that precluded removing a disk-shaped sample for testing. Therefore, 24 DINP-containing articles were tested for DINP content and migration rate by the JRC method. The DINP content ranged from 12.86 to 39.38 percent by weight, with a mean of 30 percent. Migration rates ranged from 1.05 to 11.09 $\mu\text{g}/10\text{ cm}^2/\text{min}$ with a mean of $4.1 \pm 2.7\ \mu\text{g}/10\text{ cm}^2/\text{min}$ ($269\ \mu\text{g}/11\text{ cm}^2/\text{h}$) and a median of $3.4\ \mu\text{g}/10\text{ cm}^2/\text{min}$. As in previous studies, the migration rate did not correlate well with the total DINP content of the object.

The CPSC Laboratory staff used the JRC method (*in vitro*) to test disks cut from toys identical to those used in the 1998 CPSC human subjects (*in vivo*) study as described in the 1998 DINP risk assessment. The mean *in vitro* migration rate of the toys tested in the 1998 study was 7.5 ± 0.95

⁴ *In vivo* studies are studies in which humans actually sucked on and chewed toys or standard disks and the migration of the phthalates was measured by analyzing the saliva of the individuals.

$\mu\text{g}/10\text{ cm}^2/\text{min}$ ($496\ \mu\text{g}/11\text{ cm}^2/\text{h}$) which is roughly double the *in vivo* migration rate of $241\ \mu\text{g}/11\text{ cm}^2/\text{h}$. Since the *in vitro* method results in migration rates that are double the *in vivo* rates, when the *in vitro* rates are used in the risk assessment, they are divided by two to more accurately represent the *in vivo* rate.

DINP Risk Assessment

In order to determine what risk, if any, is posed to young children from mouthing DINP-containing products, the behavioral observation data and the data detailing migration of DINP from products were used to calculate oral intake of DINP by young children. Although the petition addressed both toys and other children's products, the risk assessment only addressed toys that are mouthed since they would pose the greatest risk. A detailed description of how oral intake among young children was calculated is found at TAB K. A detailed hazard analysis, exposure and risk assessment are found at TAB L.

CPSC staff agreed with the majority of the conclusions of the CHAP. There are two areas, however, in which there are differences between the staff risk assessment and the CHAP report. One is the area of dermal exposure and the other is the actual risk posed.

The CHAP report considered dermal exposure from PVC raincoats and footwear. The report described two different approaches to estimating potential dermal exposure to DINP. One is based upon studies done in rats with PVC film containing DEHP, another phthalate having similar properties to DINP. Based upon this approach, the CHAP concluded that a negligible amount of DINP would be dermally absorbed and considered the amount insignificant for risk characterization. The second approach is based upon estimating the "effective" permeability constant. This model was based on data with compounds having $\log K_{ow}$ ⁵ values up to 4.11. A similar model was based on data with compounds with $\log K_{ow}$ values up to 6. DINP has a $\log K_{ow}$ value of ≥ 9 . This model predicts a high permeability coefficient for DINP based on the high $\log K_{ow}$. Since the K_{ow} value is high, that would mean that the chemical is hydrophobic, it likes a non-aqueous environment. This model predicts that for such a chemical, the permeability would be high. However, this model has not been validated at high K_{ow} values such as exhibited by DINP. Further, the permeability coefficient predicted for DINP by this model is not consistent with the low absorption rates measured *in vivo*. For this reason the majority of the CHAP favored the first approach, as does CPSC staff. Thus, the majority of the CHAP as well as the CPSC staff consider dermal exposure to be negligible.

The CHAP report indicated that for a subset of children who mouth toys more than 75 minutes per day, the ADI of $120\ \mu\text{g}/\text{kg}\text{-d}$ would be exceeded. The ADI is the Acceptable Daily Intake, an estimate of the amount of chemical a person can be exposed to on a daily basis over an extended period of time (up to a lifetime) with a negligible risk of suffering deleterious effects. It is expressed in units of micrograms per kilogram body weight per day. Based upon the results of the CPSC observation study which was not complete when the CHAP met, CPSC staff believes it is very unlikely that children will mouth soft plastic toys for more than 75 minutes per day. Exposures were determined by CPSC staff based upon the new observation study and the

⁵ Octanol/water partition coefficient-this measures whether a chemical prefers an aqueous or non-aqueous environment

new migration data. For a conservative estimate, it was assumed that all soft plastic toys contain DINP even though only 35% of the samples tested contained DINP. Using this assumption, for soft plastic toys, the mean exposure among 12 to 24-month-olds was 0.22 (0.11-0.32) $\mu\text{g}/\text{kg}\cdot\text{d}$ with a 95th percentile of 1.11 (0.62-1.57) $\mu\text{g}/\text{kg}\cdot\text{d}$. Numbers in parentheses are 95 percent confidence intervals. The median exposure was 0.01 (0-0.05) $\mu\text{g}/\text{kg}\cdot\text{d}$ reflecting that 42 percent of 12 to 24-month-old children in the observational study did not mouth soft plastic toys. For “all toys, teething, and rattles,” exposure was greatest among 3 to 12-month-old children. The mean exposure was 2.91 (1.83-4.26) $\mu\text{g}/\text{kg}\cdot\text{d}$, while the median was 1.45 (0.87-2.28) $\mu\text{g}/\text{kg}\cdot\text{d}$ and the 95th percentile exposure was 10.71 (6.54-16.07) $\mu\text{g}/\text{kg}\cdot\text{d}$. Table 3 summarizes the estimated oral exposure to children of various ages to DINP in children’s products.

Although pacifiers do not currently contain dialkyl phthalates, a risk assessment was done for pacifiers assuming they contained DINP and that DINP migrated at a rate seen in soft plastic toys. Estimates of the oral exposure from pacifiers are higher than other products, but are also below the ADI values. For example, the 99th percentile exposure for 3 to 12-month-old children was 62.35 $\mu\text{g}/\text{kg}\cdot\text{d}$ (95% CI 28.4-101.5). Even the 95% upper confidence limit of the 99th percentile exposure for a 3 to 12-month-old (101.5 $\mu\text{g}/\text{kg}\cdot\text{d}$) is below the ADI of 120 $\mu\text{g}/\text{kg}\cdot\text{d}$.

The staff concluded that oral exposure to DINP from mouthing soft plastic toys, teething, and rattles is not likely to present a health hazard to children. Since children mouth other children’s products less than they do toys, teething and rattles and since dermal exposure is expected to be minimal, staff does not believe that other children’s products are likely to present a health hazard to children.

Lead and Cadmium

In addition to citing the toxicity of DINP as a reason to ban the use of PVC in toys and other products intended for children five years of age and under, the petitioners also cite the fact that the attorneys general in 11 states were investigating lead and cadmium levels in soft plastic vinyl toys and their contention that lead may still be found in soft vinyl (PVC) toys after CPSC urged its removal. The Commission has previously looked at the issue of lead and cadmium in soft plastic toys.

In November 1997, the Commission staff issued a report entitled, “CPSC Staff Report on Lead and Cadmium in Children’s Polyvinyl Chloride (PVC) Products.” That report detailed the results of testing the Commission staff conducted on children’s products that Greenpeace had alleged contained hazardous levels of lead and cadmium. Although some of the vinyl products identified by Greenpeace and tested by CPSC staff contained lead or cadmium, further testing and evaluation revealed that hazardous amounts of lead or cadmium were not released from the products. This means that children would not be exposed to hazardous levels. Thus, it was concluded: “...children would not be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner.” Health Canada released a report on October 30, 1997 of its investigation into lead and cadmium in certain vinyl consumer products and reached similar conclusions to the Commission staff.

Table 3. Estimated oral exposure ($\mu\text{g}/\text{kg}\cdot\text{d}$) to DINP in children's products.^a

Product	Age (months)	Mean ^b	Median	95 th Percentile
Basic Case^c				
Soft plastic toys (35% with DINP)	3-12	0.07 (0.03 - 0.13)	0.00 (0.00 - 0.00)	0.44 (0.15 - 0.82)
	12-24	0.08 (0.04 - 0.14)	0.00 (0.00 - 0.00)	0.53 (0.24 - 0.89)
	24-36	0.03 (0.01 - 0.06)	0.00 (0.00 - 0.00)	0.12 (0.04 - 0.23)
Hypothetical Cases^c				
Soft plastic toys (100% with DINP)	3-12	0.17 (0.08 - 0.29)	0.00 (0.00 - 0.02)	0.94 (0.47 - 1.54)
	12-24	0.22 (0.11 - 0.32)	0.01 (0.00 - 0.05)	1.11 (0.62 - 1.57)
	24-36	0.07 (0.02 - 0.14)	0.00 (0.00 - 0.01)	0.27 (0.12 - 0.72)
Soft plastic toys, teething, & rattles (100% with DINP)	3-12	0.45 (0.24 - 0.74)	0.05 (0.00 - 0.17)	2.15 (1.17 - 3.47)
	12-24	0.22 (0.12 - 0.34)	0.01 (0.00 - 0.06)	1.12 (0.64 - 1.72)
	24-36	0.08 (0.02 - 0.18)	0.00 (0.00 - 0.01)	0.33 (0.12 - 1.09)
All soft plastic items (100% with DINP)	3-12	0.63 (0.38 - 0.99)	0.12 (0.04 - 0.33)	2.90 (1.77 - 4.36)
	12-24	0.41 (0.26 - 0.60)	0.15 (0.07 - 0.27)	1.69 (1.06 - 2.48)
	24-36	0.37 (0.19 - 0.59)	0.08 (0.01 - 0.18)	1.70 (0.87 - 2.73)
All toys, teething, & rattles (100% with DINP)	3-12	2.91 (1.83 - 4.26)	1.45 (0.87 - 2.28)	10.71 (6.54 - 16.07)
	12-24	0.84 (0.52 - 1.23)	0.33 (0.18 - 0.55)	3.35 (2.11 - 4.97)
	24-36	0.28 (0.15 - 0.44)	0.08 (0.04 - 0.14)	1.25 (0.59 - 2.08)
Pacifiers (100% with DINP)	3-12	4.75 (2.21 - 8.00)	0.00 (0.00 - 0.64)	24.55 (11.74 - 41.37)
	12-24	2.82 (1.19 - 5.00)	0.00 (0.00 - 0.00)	17.44 (6.44 - 30.84)
	24-36	1.71 (0.07 - 4.33)	0.00 (0.00 - 0.00)	5.41 (0.00 - 31.37)

^a From Greene (2002) (TAB K).

^b Numbers in parentheses are 95% confidence intervals.

^c See text.

International Activities

When U.S. manufacturers and distributors agreed in late 1998 to voluntarily remove phthalates from children's products intended to be mouthed, Canadian manufacturers and distributors also agreed to do the same.

In September 1999, the Commission of the European Communities issued a temporary ban of phthalates in children's products intended to be mouthed by children under 3 years of age. This ban has been extended and remains in effect. Precautionary labeling is required on children's products containing phthalates that are not intended to be mouthed. The Commission of the European Communities is currently considering legislation that would either make the ban permanent or would limit phthalate migration from these products. Some individual European states have banned phthalates either in all children's products or in products intended for mouthing.

The Japanese have added the following provisions effective August 2003 to their Manufacturing Standards for Toys: "Polyvinyl chloride that contains either di(2-ethylhexyl) phthalate or diisononyl phthalate should not be used for manufacturing of plastic toys intended mainly to be placed into the mouth of babies and/or infants."

Comments on the Petition

The Commission received 488 comments on the petition requesting a ban of polyvinyl chloride (PVC) in all toys and other products intended for children five years of age and under. A list of all the comments received can be found at TAB M. One hundred sixty-five were form letters in support of the petition and there were 311 interested parties' signatures on a form statement in support of the petition.

LEGO Systems, Inc. indicated that they were committed to a policy of phasing out the use of PVC in products and packaging, although they pointed out that they know of no credible research indicating an adverse health effect in children. They also indicated that their use of PVC was minimal and then only in toys intended for children five years of age and older. Consumer Alert urged the Commission to deny the petition, stating that the scientific evidence did not support a ban.

Comment: Ascent Pediatrics, Inc. requested that if the petition is granted, the Commission should exempt the use of phthalates and PVC formulations for use in pharmaceutical products and packaging and food packaging regardless of the age group intended for the product.

Response: Issues related to the chronic toxicity of pharmaceutical products and packaging and food packaging generally fall under the regulatory jurisdiction of the Food and Drug Administration and are not typically within CPSC's jurisdiction. We interpret the petition to deal with children's products under Commission jurisdiction.

Comment: The Society of the Plastics Industry (SPI) and its Vinyl Institute (VI), the Chemical Manufacturer's Association Phthalate Esters Panel (CMA), the Juvenile Products Manufacturers Association, the Childrenswear Marketing Association, and the Toy Manufacturers of America recommended rejection of the petition because, according to them, its request is unsupported by evidence. Further, they stated that it was premature to act on the petition until the CHAP findings are reported. Finally, some of the commenters stated that even if it were shown that children could be exposed to a harmful substance in vinyl children's products, it would not be appropriate to ban all vinyl children's products but rather it would be appropriate to establish a reasonable, technically supported performance requirement.

Response: The Commission staff agreed that it should not respond to the petition until the CHAP report was received. Although the petition requested a ban of all PVC products intended for children five and under, the reasons given were primarily the toxicity of DINP. SPI and the VI are correct that if the Commission found that DINP posed a health risk, it would likely establish a technically supported performance requirement rather than ban all vinyl products.

Comment: The CMA recommended the CPSC should modify its ADI for DINP from 0.15 mg/kg-day⁶ to 0.9 mg/kg-day.

Response: The CMA had an opportunity to present to the CHAP their position that the ADI should be 0.9 mg/kg-day (90 µg/kg-d). The CHAP concluded that the ADI should be calculated using a benchmark dose and they derived an ADI of 0.12 mg/kg-day (120 µg/kg-d). Commission staff agrees with the CHAP that the ADI should be 0.12 mg/kg-day (120 µg/kg-d). Furthermore, the Scientific Committee on Toxicity, Ecotoxicity, and the Environment (CSTEE) of the European Commission agreed with the approach of the CHAP and recommended that the European tolerable daily intake (TDI) be changed from 0.9 mg/kg-d (90 µg/kg-d) to 0.12 mg/kg-d (120 µg/kg-d) (CSTEE 2001).

Comment: The Attorneys General of the States of Arizona, California, Florida, Illinois, New York, Oklahoma, Pennsylvania, Vermont, and Wisconsin, the Georgia Office of Consumer Affairs, and the District of Columbia Office of the Corporation Counsel (collectively referred to as "the States") submitted comments requesting that the Commission immediately convene a CHAP to assess the carcinogenicity of DINP. They also urged the Commission to conduct an observation study.

Response: The Commission convened a CHAP and also conducted an observation study.

Comment: The States also commented about the level of exposure the Commission used to estimate the risk to young children from DINP-containing products in 1998. They objected to the Commission disregarding the time spent mouthing pacifiers in the exposure calculation and the statistical analysis that was done to obtain the geometrical mean exposure value used in the risk assessment. Additionally, they pointed to the much higher exposure calculated in Health

⁶ The CMA has expressed the ADI in mg/kg-d. In the rest of the document, staff has expressed the ADI in µg/kg-d. To convert mg/kg-d to µg/kg-d, the mg/kg-d value should be multiplied by 1000. Therefore, .15 mg/kg-d is the same as 150 µg/kg-d.

Canada's risk assessment and questioned the Commission's risk assessment on that basis. In a separate comment the Chemical Manufacturer's Association (CMA) stated that they believed that Health Canada's risk assessment was seriously flawed.

Response: In the current risk assessment, Commission staff calculated what the exposure to young children would be if they mouthed DINP-containing pacifiers. Although pacifiers do not contain any phthalates, assumptions were made that the migration rates of DINP out of pacifiers would be similar to the migration rates out of soft plastic toys if pacifiers contained DINP. If pacifiers contained DINP, the 99th percentile exposure would be below the ADI.

"The States" also pointed out that when the geometric mean was calculated, the mean mouthing times for 5-month-olds, 7-month-olds, 8-month-olds and 10-month-olds were higher than the geometric mean. CPSC staff notes that there were also mean mouthing times for particular ages that were less than the geometric mean. Further, the statistical technique used in the earlier risk assessment (geometric means) (CPSC, 1998) is not being used this time.

In the 1998 DINP risk assessment, CPSC fit lognormal distributions to mouthing time data, scaling factors and migration rates. The lognormal distributions are completely specified by the mean and variance of the logarithms of the data. Exponentiating the estimate for the mean produces the geometric mean of the data. This statistic is similar to the median as the measure of the center of the data. Values for geometric means were reported in the 1998 risk assessment. With these means and variances, it was possible to combine the distribution of mouthing time data, scaling factors and migration rates into a single distribution of DINP intake in closed form, i.e. where the mathematical formula could be written down. Computer routines to calculate this formula were used to develop point estimates for percentiles. Associated confidence intervals involved the parametric bootstrap (Efron and Tibshirani, 1993).

The approach in the 1998 risk assessment was defined by the type and quality of the data that was available. CPSC staff could have used the same type of Monte Carlo procedure as the Dutch Consensus group (they used the same mouthing data), but lack of confidence in the data made it important to smooth out the data with a probability distribution. Of most concern was the mouthing data. It was collected from a convenience sample, parents rather than professional observers obtained the data, the mouthing time categories included objects that were not made from soft plastic or did not contain DINP, and while the sample was from a small city in Holland it was purported to represent mouthing behavior among US children. These concerns resulted in the new children's observational study.

Increased confidence in the new data allowed for a different approach to modeling risk. The new mouthing data is from an American probability sample, with professional observers and the ability to identify soft plastic toys. The DINP migration rates are from soft plastic toys and use the latest methodology that produces rates close to *in vivo* levels. With much more confidence in the data, a more accurate Monte Carlo approach that uses all the data, rather than just the means and standard deviations was appropriate. The approach is non parametric in the sense that no statistical distributions are used to represent the critical variables of mouthing times and migration rates. Rather the actual data from the children and the CPSC lab are used in the computation of percentiles and associated confidence intervals of DINP intake.

Finally, the Health Canada estimate to which “the States” refer was an upper bound estimate, which was based on the highest migration rate from the Dutch in vivo chew and spit study, a 3-hour exposure time, and the 5th percentile body weight. Based upon data from all the observation studies including the most recent CPSC work, which is the most extensive mouthing study to date, we believe that a 3-hour exposure time is not likely to occur. We believe that our new estimates more accurately reflect DINP exposure than do the Health Canada and other previous estimates.

Comment: “The States” also indicated that the Commission needs to do further work to determine whether the lead and/or cadmium present in PVC products poses a risk to children. The Lead Industries Association commented that a ban of PVC in toys based upon exposure to lead and cadmium in these products was not justified scientifically. The CMA cited CPSC’s previous work to rebut the claim that lead and/or cadmium in PVC products pose a risk to children.

Response: In order for a chemical to be a “hazardous substance” by reason of toxicity it must: 1) have the capacity to produce personal injury or illness when evaluated according to the criteria established in 16CFR part 1500; and 2) must have the potential to cause substantial personal injury or illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children. The mere presence of a chemical in products is not sufficient to classify it as a hazardous substance. In November 1997, the Commission staff issued a report entitled, “CPSC Staff Report on Lead and Cadmium in Children’s Polyvinyl Chloride (PVC) Products.” In the report it was concluded: “...children would not be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner.” Health Canada released a report on October 30, 1997 of its investigation into lead and cadmium in certain vinyl consumer products and reached similar conclusions to the Commission staff. None of the issues “The States” raised about the manner in which the lead and cadmium testing were done would alter these conclusions. No data were presented that would alter the Commission staff conclusion or that would justify a ban of PVC products based upon lead and/or cadmium exposure.

Options

The request consisted of two parts. The first part, that was docketed as petition HP 99-1, requested the ban of PVC in all toys and other products intended for children five years of age and under. The reasons given for this request focussed on the use of chemical softeners and metal stabilizers that, according to the petitioners, “have been linked to potentially serious health effects” in PVC used in children’s toys. The chemical softener and metal stabilizers specifically mentioned were DINP, lead, and cadmium. The second part requested a national advisory on the health risks that have been associated with PVC toys to advise parents and consumers about the risks associated with PVC toys currently in the stores and homes.

The Commission has the following options:

A. Grant the Petition and Issue a National Health Advisory

If the Commission determines that there is an unreasonable risk of injury to children five years and under resulting from exposure to PVC in toys and other products, the Commission could grant the petition. The Commission could instruct the staff to begin a rulemaking proceeding to ban PVC in all toys and other products intended for children five years and under. The Commission could also instruct the staff to develop a national advisory warning parents about the risks of PVC toys for Commission consideration.

B. Deny the Petition and Decline to Issue a National Health Advisory

If the Commission finds that currently available information would not support a finding of unreasonable risk of injury to children five years of age and under resulting from exposure to PVC in toys and other products intended for children five years of age and under, the Commission could deny the petition and decline to issue a national health advisory.

Recommendation and Discussion

The staff recommends that the Commission deny the petition and decline to issue the national health advisory. In 1997, the Commission staff investigated the claim that the use of lead and cadmium in PVC poses a risk of injury to children and concluded for the products tested, "...children would not be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner." No data were provided to change that conclusion.

With regard to DINP, the CHAP, convened by the Commission, concluded, "For the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury." The new data from the CPSC behavioral observation study, which were not available to the CHAP, confirm this conclusion and demonstrate that children are exposed to DINP at even lower levels than the CHAP members assumed when they reached their conclusion. Further, in a recent review of toys mouthed by children under the age of three, staff determined that not all soft plastic toys contain DINP. Therefore, exposure would be even less than the CHAP predicted because children mouth these toys for less time per day than the CHAP estimated, and the average amount of DINP in toys mouthed by children under the age of three is less than the CHAP estimated. Further, if the risk to children under the age of three is not sufficient to warrant action, then based upon the data collected for this study, and the data available in published literature, which indicates that mouthing declines as children age, there would be no justification for taking action on toys intended for children from 36 through 71 months old. Also, since children mouth other products even less than they mouth toys and dermal exposure is expected to be negligible, there would be no justification for taking action against other products intended for children five years old and younger.

Based upon the scientific data presented in this briefing package, the staff believes that there is no demonstrated health risk posed by PVC toys or other products intended for children five years

of age and under and thus, no justification for either banning PVC use in toys and other products intended for children five years of age and under or for issuing a national advisory on the health risks associated with soft plastic toys.

TAB A

11/19/98
for [unclear]

NATIONAL ENVIRONMENTAL TRUST

1200 Eighteenth Street, NW, Fifth Floor
Washington, DC 20036
202-887-8800 - 887-8877 fax

CPSC/OFFICE OF
THE SECRETARY

1998 NOV 20 P 2:27

November 19, 1998

Office of the Secretary
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20899

Please accept the attached petition to initiate a Commission rulemaking to ban polyvinyl chloride (PVC) from all toys and products intended for children five years of age and under and to issue a national advisory on the health risks that have been associated with PVC toys and products.

Attachments to this request include:

"A Select Annotated Bibliography on the Toxicity of Diisononyl Phthalate (DINP) and its Migration from Children's Products," Barbara Bass, National Environmental Trust, October 1998.

"Determination of the Composition and Quantity of Phthalate Ester Additives in PVC Children's Toys," Stringer et al., Greenpeace Research Laboratories, September 1997.

"Lead and Cadmium in Vinyl Children's Products," Joseph Di Gangi, Greenpeace.

"Report on DINP Phthalate: Summary of the Published Literature and Quantities Found in Common Toys," Thomas Natan, National Environmental Trust, November 1998.

"Toxic Chemicals in Vinyl Children's Toys," Greenpeace, November 1998.

98 NOV 20 P 2:39

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CPSC
GENERAL OFFICE

Office of the Secretary/Page Two

The petitioners listed below request information about the progress and disposition of this petition at the Commission's earliest opportunity. The Commission may notify petitioners through the following contact person: Jeffrey Becker Wise, Policy Director, National Environmental Trust, 1200 18th Street, N.W., Suite 500, Washington, DC, 20036 (202-887-8800).

Sincerely,

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Director
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Mary Ellen Fise
General Counsel
Consumer Federation of America

Ed Hopkins
Vice President
Environmental Working Group

Rick Hind
Legislative Director
Toxics Campaign
Greenpeace USA

Justine Maloney
Washington Representative
Learning Disabilities Association

Sheila McCarron
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National Council of Catholic Women

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National Council of Jewish Women

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Jaydee Hanson
Assistant General Secretary
United Methodist Church—
General Board of Church and Society

Pamela Spar
Executive Secretary
United Methodist Church—
Women's Division

Gene Karpinski
Executive Director
U.S. Public Interest Research Group

The undersigned call on the Consumer Product Safety Commission to:

- I. Institute an immediate ban on polyvinyl chloride (PVC) in all toys and other products intended for children five years of age and under;
- II. Issue a national advisory on the health risks that have been associated with soft plastic vinyl (PVC) toys to inform parents and consumers about the risks associated with PVC toys currently in stores and homes.

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TAB B



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

OFFICE OF THE GENERAL COUNSEL

Stephen Lemberg
Assistant General Counsel
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July 9, 2001

Mr. Rick Hind
Legislative Director
Greenpeace Toxics Campaign
702 H St., N.W., Suite 300
Washington, DC 20001

Dear Mr. Hind:

Your submission to Ann Brown dated June 6, 2001 has been forwarded to the Office of the General Counsel for a determination as to whether some or all of it meets Commission requirements set forth in 16 CFR part 1051 for docketing as a petition for rulemaking. The submission requests that the Commission take the following specific actions:

- Immediately issue a warning in the Federal Register advising manufacturers, retailers and distributors and parents to end the unnecessary production, sale and use, respectively, of vinyl consumer products
- Begin regulating vinyl (PVC plastics) as a hazardous material
- Prohibit the use of all phthalates and organotins, in addition to lead, cadmium and other toxic or untested additives, in all consumer products

For the reasons discussed below, these requests do not meet statutory or Commission regulatory requirements for docketing as petitions for rulemaking.

1. Issue Federal Register warning concerning vinyl consumer products

You request that the Commission "immediately issue a warning in the Federal Register advising manufacturers, retailers and distributors and parents to end the unnecessary production, sale and use respectively, of vinyl consumer products." This request would not require

rulemaking to implement and accordingly is not being docketed as a petition for rulemaking under the Commission's rules. 16 CFR 1051.5(a)(5).

A more fundamental problem with the requested warning is that it is unclear from your submission on what factual basis or under what authority the Commission might issue it. Finally, the submission does not contain information sufficient to determine to which specific consumer products such a warning might refer.

2. Begin regulating "vinyl (PVC plastics)" as a hazardous material

You request that the Commission "begin regulating vinyl (PVC plastics) as a hazardous material." Such a request would most likely be addressed via rulemaking under the Federal Hazardous Substances Act (FHSA).¹ To make a determination under § 2(f)(1)(A) of the FHSA that "vinyl (PVC plastics)" are a "hazardous substance," the Commission must find that all such items are "toxic," and that they "may cause substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including foreseeable ingestion by children."²

Section 3(a)(2) of the FHSA requires that a rulemaking, such as the one that is the subject of this request, be conducted in accordance with § 701(e) of the Federal Food, Drug, and Cosmetic Act (FDCA).³ Under § 701(e), for the Commission to proceed to rulemaking, the petition must set forth "reasonable grounds" for the requested action. The United States Court of Appeals for the District of Columbia Circuit has held that "reasonable grounds" for a petition under the FHSA "are grounds from which it is reasonable to conclude that the Commission would be able to make the findings required to issue the requested rule and to support those findings with substantial evidence on the record."⁴ A submission must identify "the product (or products) regulated under the Consumer Product Safety Act or other statute the Commission administers for which a rule is sought." 16 CFR 1051.5(a)(3). A submission must "set forth facts which establish the claim that the issuance of the rule is necessary." 16 CFR 1051.5(a)(4). "A general request for regulatory action which does not reasonably specify the type of action requested shall not be sufficient for purposes of this subsection." 16 CFR 1051.5(a)(5).

Your request does not identify the specific consumer products of concern within the broad category of "vinyl (PVC plastics)," the specific toxic constituent(s) and their concentration(s) in each product of concern, the mechanism of exposure to and/or uptake of each such constituent, or the "substantial illness" that might result from customary or reasonably foreseeable handling or use of each such product -- all of which would be necessary predicates for a Commission determination that such a product or products were "hazardous substances" for purposes of the FHSA. Thus, this portion of the submission does not satisfy the statutory

¹ In the absence of special circumstances, the Commission would be required by § 30(d) of the Consumer Product Safety Act (CPSA) to conduct the requested rulemaking under the FHSA as opposed to the CPSA. Gulf South Insulation v. CPSC, 701 F.2d 1137 (5th Cir. 1983).

² 15 U.S.C. 1261(f)(1)(A).

³ 15 U.S.C. 1262(a)(2).

⁴ Consumer Federation of America v. CPSC, 883 F.2d 1073, 1076 (D.C. Cir. 1989).

Mr. Rick Hind

July 9, 2001

Page 3

"reasonable grounds" and other criteria and does not qualify under Commission rules to be docketed as a petition for rulemaking.

3. Prohibit the use of all phthalates and organotins, in addition to lead, cadmium, and other toxic or untested additives in all consumer products

You request that the Commission "prohibit the use of all phthalates and organotins, in addition to lead, cadmium and other toxic or untested additives in all consumer products." To issue a ban under the FHSA, the Commission must first determine, as noted above, that the product at issue is a "hazardous substance." Having made the hazardous substance determination, the Commission must then find with respect to each such product (other than a toy or other article intended for the use of children) that:

[N]otwithstanding such cautionary labeling as is or may be required under this Act [the FHSA] for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of public health and safety can be adequately served only by keeping such substance ... out of the channels of interstate commerce.

FHSA § 2(q)(1)(B); 15 U.S.C. 1261(q)(1)(B).

Section 2(q)(1)(B) is the appropriate section of the FHSA under which to consider the request for a ban in light of the statement in the submission that it is intended to address "all PVC products used in the home," whether or not "intended for use by children." Section 2(q)(1)(A) applies only to products intended for use by children.

As with the prerequisite "hazardous substances" determination, a ban determination under § 2(q)(1)(B) must be accomplished using the procedures of § 701(e) of the FDCA.⁵ Thus, your request for a ban is also subject to the "reasonable grounds" test of § 701(e).⁶

The submission does not provide information sufficient to identify: 1) any specific substances within the generally stated categories of "all phthalates and organotins, in addition to lead, cadmium and other toxic or untested additives;" 2) the specific products of concern; 3) the pertinent toxic constituent(s) or their concentration(s) in each product of concern; 4) the mechanism of exposure to and/or uptake of each such constituent; or 5) the "substantial illness" that might result from customary or reasonably foreseeable handling or use of each such product — all necessary predicates for a Commission determination that each is a "hazardous substance" for purposes of the FHSA.⁷

⁵ FHSA § 2(q)(2); 15 U.S.C. 1261(q)(2).

⁶ 21 U.S.C. 371(e).

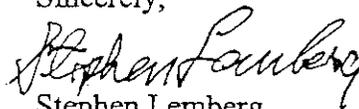
⁷ With respect to diisononyl phthalate (DINP), which is mentioned specifically in the submission, the Chronic Hazard Advisory Panel appointed by the Commission to address risks posed by DINP submitted its report, copy enclosed, to the Commission on June 15, 2001. Among other things, that report states:

Mr. Rick Hind
July 9, 2001
Page 4

With respect to the requested ban, the submission does not provide information regarding any constituent or product explaining why the degree or nature of the hazard involved in the presence or use of such product in households is such that the objective of the protection of public health and safety can be adequately served only by banning it. Accordingly, the request for a ban does not satisfy the previously discussed "reasonable grounds" criterion as to a petition for rulemaking under § 2(q)(1)(B) of the FHSA.

For the reasons given above, we are unable to docket your requests as petitions for rulemaking at this time. If you desire to make another submission to the CPSC requesting action concerning use of PVC in consumer products, please address the issues raised in this letter. Any such subsequent submission will be considered accordingly under the criteria of the FHSA and the Commission's rules at 16 CFR part 1051 for docketing of petitions for rulemaking. To assist you in that regard, a copy of these regulations is enclosed. In the meantime, I appreciate your sharing your concerns with the Commission.

Sincerely,


Stephen Lemberg

Enclosures

The CHAP concludes that humans do not currently receive DINP doses from DINP-containing consumer products that are plausibly associated with a significant increase in cancer risk.

Report to the U.S. Consumer Product Safety Commission by the CHRONIC HAZARD ADVISORY PANEL ON DIISONONYL PHTHALATE (DINP), June 2001, at 5.

Thus, with respect to a ban on use of DINP in consumer products, it would be necessary for the submission to contain information sufficient to enable the Commission to reasonably determine that this conclusion of the CHAP was incorrect.

Consumer Product Safety Commission

§ 1051.1

Commission in 29 CFR part 1613 pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

(c) The Office of Equal Employment Opportunity and Minority Enterprise shall be responsible for coordinating implementation of this section. Complaints may be sent to the Director, Office of Equal Employment Opportunity and Minority Enterprise, Consumer Product Safety Commission, Washington, D.C. 20207.

(d) The agency shall accept and investigate all complete complaints for which it has jurisdiction. All complete complaints must be filed within 180 days of the alleged act of discrimination. The agency may extend this time period for good cause.

(e) If the agency receives a complaint over which it does not have jurisdiction it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate government entity.

(f) The agency shall notify the Architectural and Transportation Barriers Compliance Board upon receipt of any complaint alleging that a building or facility that is subject to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157), or section 502 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 792), is not readily accessible to and usable by handicapped persons.

(g) Within 180 days of the receipt of a complete complaint for which it has jurisdiction, the agency shall notify the complainant of the results of the investigation in a letter containing—

(1) Findings of fact and conclusions of law;

(2) A description of a remedy for each violation found; and

(3) A notice of the right to appeal.

(h) Appeals of the findings of fact and conclusions of law or remedies must be filed by the complainant within 90 days of receipt from the agency of the letter required by § 1034.170(g). The agency may extend this time for good cause.

(i) Timely appeals shall be accepted and processed by the head of the agency.

(j) The head of the agency shall notify the complainant of the results of the appeal within 60 days of the receipt of the request. If the head of the agen-

cy determines that additional information is needed from the complainant, he or she shall have 60 days from the date of receipt of the additional information to make his or her determination on the appeal.

(k) The time limits cited in paragraphs (g) and (j) of this section may be extended with the permission of the Assistant Attorney General.

(l) The agency may delegate its authority for conducting complaint investigations to other Federal agencies, except that the authority for making the final determination may not be delegated to another agency.

[51 FR 4575, 4579, Feb. 5, 1986, as amended at 51 FR 4575, Feb. 5, 1986]

§§ 1034.171-1034.999 [Reserved]

PART 1051—PROCEDURE FOR PETITIONING FOR RULEMAKING

Sec.

1051.1 Scope.

1051.2 General.

1051.3 Place of filing.

1051.4 Time of filing.

1051.5 Requirements and recommendations for petitions.

1051.6 Documents not considered petitions.

1051.7 Statement in support of or in opposition to petitions; Duty of petitioners to remain apprised of developments regarding petitions.

1051.8 Public hearings on petitions.

1051.9 Factors the Commission considers in granting or denying petitions.

1051.10 Granting petitions.

1051.11 Denial of petitions.

AUTHORITY: 5 U.S.C. 553(e), 5 U.S.C. 555(e).

SOURCE: 48 FR 57123, Dec. 28, 1983, unless otherwise noted.

§ 1051.1 Scope.

(a) This part establishes procedures for the submission and disposition of petitions for the issuance, amendment or revocation of rules under the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051 *et seq.*) or other statutes administered by the Consumer Product Safety Commission.

(b) Persons filing petitions for rulemaking shall follow as closely as possible the requirements and are encouraged to follow as closely as possible the recommendations for filing petitions under § 1051.5.

(c) Petitions regarding products regulated under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261 *et seq.*) are governed by existing Commission procedures at 16 CFR 1500.82. Petitions regarding the exemption of products regulated under the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471 *et seq.*) are governed by existing Commission procedures at 16 CFR part 1702. In addition, however, persons filing such petitions shall follow the requirements and are encouraged to follow the recommendations for filing petitions as set forth in § 1051.5.

[48 FR 57123, Dec. 28, 1983 as amended at 64 FR 48704, Sept. 8, 1999]

§ 1051.2 General

(a) Any person may file with the Commission a petition requesting the Commission to begin a proceeding to issue, amend or revoke a regulation under any of the statutes it administers.

(b) A petition which addresses a risk of injury associated with a product which could be eliminated or reduced to a sufficient extent by action taken under the Federal Hazardous Substances Act, the Poison Prevention Packaging Act of 1970, or the Flammable Fabrics Act may be considered by the Commission under those Acts. However, if the Commission finds by rule, in accordance with section 30(d) of the CPSA, as amended by Public Law 94-284, that it is in the public interest to regulate such risk of injury under the CPSA, it may do so. Upon determination by the Office of the General Counsel that a petition should be considered under one of these acts rather than the CPSA, the Office of the Secretary shall docket and process the petition under the appropriate act and inform the petitioner of this determination. Such docketing, however, shall not preclude the Commission from proceeding to regulate the product under the CPSA after making the necessary findings.

§ 1051.3 Place of filing.

A petition should be mailed to: Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207. Persons wishing to file a petition

in person may do so in the Office of the Secretary, at 4330 East West Highway, Bethesda, Maryland.

[48 FR 57123, Dec. 28, 1983, as amended at 62 FR 46667, Sept. 4, 1997]

§ 1051.4 Time of filing.

For purposes of computing time periods under this part, a petition shall be considered filed when time-date stamped by the Office of the Secretary. A document is time-date stamped when it is received in the Office of the Secretary.

§ 1051.5 Requirements and recommendations for petitions.

(a) *Requirements.* To be considered a petition under this part, any request to issue, amend or revoke a rule shall meet the requirements of this paragraph (a). A petition shall:

(1) Be written in the English language;

(2) Contain the name and address of the petitioner;

(3) Indicate the product (or products) regulated under the Consumer Product Safety Act or other statute the Commission administers for which a rule is sought or for which there is an existing rule sought to be modified or revoked. (If the petition regards a procedural or other rule not involving a specific product, the type of rule involved must be indicated.)

(4) Set forth facts which establish the claim that the issuance, amendment, or revocation of the rule is necessary (for example, such facts may include personal experience; medical, engineering or injury data; or a research study); and

(5) Contain an explicit request to initiate Commission rulemaking and set forth a brief description of the substance of the proposed rule or amendment or revocation thereof which it is claimed should be issued by the Commission. (A general request for regulatory action which does not reasonably specify the type of action requested shall not be sufficient for purposes of this subsection.)

(b) *Recommendations.* The Commission encourages the submission of as much information as possible related to the petition. Thus, to assist the Commission in its evaluation of a petition, to

the extent the information is known and available to the petitioner, the petitioner is encouraged to supply the following information or any other information relating to the petition. The petition will be considered by the Commission even if the petitioner is unable to supply the information recommended in this paragraph (b). However, as applicable, and to the extent possible, the petitioner is encouraged to:

(1) Describe the specific risk(s) of injury to which the petition is addressed, including the degree (severity) and the nature of the risk(s) of injury associated with the product and possible reasons for the existence of the risk of injury (for example, product defect, poor design, faulty workmanship, or intentional or unintentional misuse);

(2) State why a consumer product safety standard would not be feasible if the petition requests the issuance of a rule declaring the product to be a banned hazardous product; and

(3) Supply or reference any known documentation, engineering studies, technical studies, reports of injuries, medical findings, legal analyses, economic analyses and environmental impact analyses relating to the petition.

(c) *Procedural recommendations.* The following are procedural recommendations to help the Commission in its consideration of petitions. The Commission requests, but does not require, what a petition filed under this part:

(1) Be typewritten,

(2) Include the word "petition" in a heading preceding the text,

(3) Specify what section of the statute administered by the Commission authorizes the requested rulemaking,

(4) Include the telephone number of the petitioner, and

(5) Be accompanied by at least five (5) copies of the petition.

§ 1051.6 Documents not considered petitions.

(a) A document filed with the Commission which addresses a topic or involves a product outside the jurisdiction of the Commission will not be considered to be a petition. After consultation with the Office of the General Counsel, the Office of the Secretary, if appropriate, will forward to the appro-

appropriate agency documents which address products or topics within the jurisdiction of other agencies. The Office of the Secretary shall notify the sender of the document that it has been forwarded to the appropriate agency.

(b) Any other documents filed with the Office of the Secretary that are determined by the Office of the General Counsel not to be petitions shall be evaluated for possible staff action. The Office of the General Counsel shall notify the writer of the manner in which the Commission staff is treating the document. If the writer has indicated an intention to petition the Commission, the Office of the General Counsel shall inform the writer of the procedure to be followed for petitioning.

§ 1051.7 Statement in support of or in opposition to petitions; Duty of petitioners to remain apprised of developments regarding petitions.

(a) Any person may file a statement with the Office of the Secretary in support of or in opposition to a petition prior to Commission action on the petition. Persons submitting statements in opposition to a petition are encouraged to provide copies of such statements to the petitioner.

(b) It is the duty of the petitioner, or any person submitting a statement in support of or in opposition to a petition, to keep himself or herself apprised of developments regarding the petition. Information regarding the status of petitions is available from the Office of the Secretary of the Commission.

(c) The Office of the Secretary shall send to the petitioner a copy of the staff briefing package on his or her petition at the same time the package is transmitted to the Commissioners for decision.

§ 1051.8 Public hearings on petitions.

(a) The Commission may hold a public hearing or may conduct such investigation or proceeding, including a public meeting, as it deems appropriate to determine whether a petition should be granted.

(b) If the Commission decides that a public hearing on a petition, or any portion thereof, would contribute to its determination of whether to grant or

deny the petition, it shall publish in the FEDERAL REGISTER a notice of a hearing on the petition and invite interested persons to submit their views through an oral or written presentation or both. The hearings shall be informal, nonadversary, legislative-type proceedings in accordance with 16 CFR part 1052.

§ 1051.9 Factors the Commission considers in granting or denying petitions.

(a) The major factors the Commission considers in deciding whether to grant or deny a petition regarding a product include the following items:

(1) Whether the product involved presents an unreasonable risk of injury.

(2) Whether a rule is reasonably necessary to eliminate or reduce the risk of injury.

(3) Whether failure of the Commission to initiate the rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the risk of injury which the petitioner alleges is presented by the product.

(4) Whether, in the case of a petition to declare a consumer product a "banned hazardous product" under section 8 of the CPSA, the product is being or will be distributed in commerce and whether a feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with such product.

(b) In considering these factors, the Commission will treat as an important component of each one the relative priority of the risk of injury associated with the product about which the petition has been filed and the Commission's resources available for rulemaking activities with respect to that risk of injury. The CPSC Policy on Establishing Priorities for Commission Action, 16 CFR 1009.8, sets forth the criteria upon which Commission priorities are based.

§ 1051.10 Granting petitions.

(a) The Commission shall either grant or deny a petition within a reasonable time after it is filed, taking into account the resources available for processing the petition. The Com-

mission may also grant a petition in part or deny it in part. If the Commission grants a petition, it shall begin proceedings to issue, amend or revoke the rule under the appropriate provisions of the statutes under its administration. Beginning a proceeding means taking the first step in the rulemaking process (issuance of an advance notice of proposed rulemaking or a notice of proposed rulemaking, whichever is applicable).

(b) Granting a petition and beginning a proceeding does not necessarily mean that the Commission will issue, amend or revoke the rule as requested in the petition. The Commission must make a final decision as to the issuance, amendment, or revocation of a rule on the basis of all available relevant information developed in the course of the rulemaking proceeding. Should later information indicate that the action is unwarranted or not necessary, the Commission may terminate the proceeding.

§ 1051.11 Denial of petitions.

(a) If the Commission denies a petition it shall promptly notify the petitioner in writing of its reasons for such denial as required by the Administrative Procedure Act, 5 U.S.C. 555(e).

(b) If the Commission denies a petition, the petitioner (or another party) can refile the petition if the party can demonstrate that new or changed circumstances or additional information justify reconsideration by the Commission.

(c) A Commission denial of a petition shall not preclude the Commission from continuing to consider matters raised in the petition.

PART 1052—PROCEDURAL REGULATIONS FOR INFORMAL ORAL PRESENTATIONS IN PROCEEDINGS BEFORE THE CONSUMER PRODUCT SAFETY COMMISSION

Sec.

1052.1 Scope and purpose.

1052.2 Notice of opportunity for oral presentation.

1052.3 Conduct of oral presentation.

1052.4 Presiding officer; appointment, duties, powers.

Report to the
U.S. Consumer Product Safety Commission
by the

CHRONIC HAZARD ADVISORY PANEL
ON DIISONONYL PHTHALATE (DINP)

June 2001

U.S. Consumer Product Safety Commission
Directorate for Health Sciences
Bethesda, MD 20814



Copy of cover page only

CONTROLLED CORRESPONDENCE FROM THE OFFICE OF SECRETARY

Control No.: OS20010166

Date Entered: 06/08/2001

Date of Corresp.: 06/06/2001

Date Due: 07/23/2001

(Return to OS by this date with all correspondence)

Date Completed: 00/00/0000

- Prepare for Chairman's Signature
- Direct Reply
- Action at your discretion
- No Response Needed
- Acknowledgement sent by OS
- Other

Name: RICK HIND

Company: GREENPEACE TOXICS
CAMPAIGN

City: WASHINGTON

State: DC

Subject: POSSIBLE PETITION: ON POLYVINYL CHLORIDE (PVC) PLASTIC TOYS

FYI Copies to:

COAB, COTM, COMG, EX, EXHR,
EXPA, OS

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PLEASE SEND COPIES OF RESPONSE TO OS

GREENPEACE

702 H Street, NW, Suite 300, Washington, DC 20001
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1-800-326-0959 • www.greenpeaceusa.org

June 6, 2001

Ms. Ann Brown, Chair
U.S. Consumer Product Safety Commission
Washington, D.C. 20207

Dear Ms. Brown,

We are writing this letter to petition the U.S. Consumer Product Safety Commission (CPSC) to expand the scope of a November 19, 1998 petition on polyvinyl chloride (PVC) plastic toys by Greenpeace and other groups to the U.S. Consumer Product Safety Commission 1. In that petition, we asked that your agency institute a ban on PVC plastic in all toys and other products intended for children five years of age and under. In addition, we urged that a national advisory be made on the health risks associated with soft PVC toys.

Given recent findings and developments discussed below, Greenpeace is calling upon the CPSC to broaden the scope of that 1998 petition to include all PVC products used in the home.

In March of this year, the European Union renewed its 1999 emergency ban on the use of six phthalates in PVC toys made for children under the age of three 2. Also since our 1998 petition, Greenpeace has conducted tests for phthalate plasticizers and organotin stabilizers in readily available PVC consumer products and home furnishings that children are likely to come into contact with in their daily lives. The results of the tests are presented in our May, 2001 report 3.

To summarize, the recent Greenpeace tests found that some of the highest levels of phthalates were found in products specifically designed for children's mouths. Other products contained the phthalate diethylhexyl phthalate (DEHP) significantly above the 3% voluntary cap set for pacifiers and teethingers. Although these products are not intended for children's mouths, some are very likely to be chewed by children. It was also discovered that diisononyl phthalate (DINP), an ill-defined chemical mixture often containing untested isomers, is used in teethingers at over 20% by weight of the product. With respect to their organotin content, all but one of the tested products contained detectable amounts. Some organotins cause nervous system damage and even death at high levels of exposure. PVC plastic is unique among all plastics due to the large quantity of toxic additives (plasticizers, stabilizers, etc.) required for its use in consumer products.

As you may recall, this problem first came to light in 1985 and 1986 when the toy industry agreed to limit the amount of one phthalate (DEHP) in PVC toys to less than 3% and again in 1996 when lead in PVC mini-blinds was found to unnecessarily put children

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at risk because the lead was released to the surface of the blinds in the form of dust which children easily handled.

In light of new European regulations on phthalates in PVC products currently in place and the finding that a wide variety of vinyl products other than toys contain hazardous phthalates and organotins, Greenpeace is calling on the CPSC to take immediate action, whether by granting this petition or interim action. The CPSC should:

Immediately issue a warning in the Federal Register similar to its 1998 guidance for lead in consumer products. The warning should advise manufacturers, retailers and distributors and parents to end the unnecessary production, sale and use, respectively, of vinyl consumer products. The warning should not be limited to products designed for children.

Begin regulating vinyl (PVC plastics) as a hazardous material.

Prohibit the use of phthalates and organotins, in addition to lead, cadmium and other toxic or untested additives in all consumer products.

On behalf of the public, Greenpeace looks forward to the CPSC's timely response to this petition.

Sincerely,

Rick Hind
Legislative Director,
Greenpeace Toxics Campaign

Enclosures (3): 1. Greenpeace. 1998. Petition to the Consumer Product Safety Commission.

European Commission. 2001. Excerpt of March 5 Decision.

Harmon. 2001. This Vinyl House: Hazardous Additives in Vinyl Consumer Products and Home Furnishings.

November 19, 1998

PETITION

To the Consumer Product Safety Commission Concerning Phthalates and PVC in Children's Toys:

Whereas soft plastic vinyl --- polyvinyl chloride (PVC) --- requires the addition of chemical softeners and hard metal stabilizers that have been linked to potentially serious health effects;

Whereas independent health studies have consistently found associations between DINP phthalate softeners in soft plastic vinyl (PVC) and liver and kidney damage;

Whereas a preliminary Consumer Product Safety Commission (CPSC) hazard assessment stated that DINP exposure was associated with ³toxic effects in the liver, kidney, and other organs of mice and rats;²

Whereas CPSC's hazard assessment of DINP stated, ³It is conceivable that one or more existing types of DINP for which data are unavailable could also be more toxic and/or carcinogenic;²

Whereas DINP phthalate is found in virtually every soft plastic vinyl (PVC) toy often at levels of 30 percent or more by weight;

Whereas four out of six studies reviewed by the European Union found levels of phthalate leaching that translated to daily exposure levels higher than the CPSC's ³acceptable daily intake level;²

Whereas existing exposure studies likely understate the extent of exposure given that children mouth, bite, and swallow plastic much more aggressively than study simulations;

Whereas eight foreign countries have taken official action on phthalates including two bans (Austria, Denmark), one pending ban (Sweden), four requests for voluntary action (Belgium, Germany, Italy, Netherlands), and one national health advisory (Canada);

Whereas the attorneys general of 11 states are conducting a joint

investigation of lead and cadmium levels in soft plastic vinyl (PVC) toys;

Whereas lead may still be found in soft vinyl (PVC) toys after the CPSC urged its removal;

Whereas some U.S. toy manufacturers and retailers have not adequately addressed the problem by acting only on toys intended for the mouth;

Whereas infants and toddlers put all toys in their mouths;

Whereas alternatives to soft plastic vinyl (PVC) are commercially available and affordable;

Whereas an April 21, 1997, Presidential Executive Order states: ³Each Federal agency shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks;²

The undersigned call on the Consumer Product Safety Commission to:

I. Institute an immediate ban on polyvinyl chloride (PVC) plastic in all toys and other products intended for children five years of age and under;

II. Issue a national advisory on the health risks that have been associated with soft plastic vinyl (PVC) toys to inform parents and consumers about the risks associated with PVC toys currently in stores and homes.

Children's Health Environmental Coalition
Nancy Chuda, Director
310-589-2233

Consumer Federation of America
Mary Ellen Fise, General Counsel
202-387-6121

Environmental Working Group
Ed Hopkins, Vice President
202-667-6982

Greenpeace USA
Rick Hind, Legislative Director (Toxics Campaign)
202-462-1177

Learning Disabilities Association
Justine Maloney, Washington Representative
703-243-2614

National Council of Catholic Women
Sheila McCarron, Program Director
202-682-0334

National Council of Jewish Women
Sammie Moshenberg, Director (Washington Office)
202-296-2588

National Environmental Trust
Philip Clapp, President
202-887-8800

Physicians for Social Responsibility
Robert K. Musil, Ph.D.
Executive Director
202-898-0150

United Methodist Church (General Board of Church and Society)
Jaydee Hanson,
Assistant General Secretary
202-488-5635

United Methodist Church
(Women's Division)
Pamela Spar, Executive Secretary
292-488-5660

U.S. Public Interest Research Group
Gene Karpinski, Executive Director
202-546-9707

TABC

Chronic Hazard Advisory Panel on Diisononyl Phthalate

Kenneth T. Bogen, M.P.H., Dr.P.H., Chairman
University of California, Livermore, CA

Kim Boekelheide, M.D., Ph.D., Vice Chairman
Brown University, Providence, RI

Michael L. Cunningham, Ph.D., DABT
National Institute of Environmental Health Sciences, National Institutes of Health,
Research Triangle Park, NC

Benjamin A. Jackson, M.S., Ph.D.
Information Ventures, Philadelphia, PA.

Jeffrey M. Peters, Ph.D.
Pennsylvania State University, University Park, PA.

Janardan K. Reddy, M.S., M.D.
Northwestern University Medical School, Chicago, IL

Lauren Zeise, Ph.D.
California Environmental Protection Agency, Berkeley, CA

TAB D

Presenters at the June 2000 CHAP Meeting

Rainer Bahnemann, D.V.M., Pathologist, BASF Corporation and member, Phthalates Ester Panel Toxicology Research Task Group

Chris Corton, Toxicologist, Chemical Industry Institute of Toxicology

Raymond M. David, Ph.D., Chairman, Phthalates Ester Panel, Toxicology Research Task Group

Jerry F. Hardisty, D.V.M., President and Pathologist, Experimental Pathology Laboratories, Inc.

Rick Hind, Legislative Director, Toxics Campaign, Greenpeace

James Klaunig, Ph.D., Professor of Pharmacology and Toxicology, Indiana University School of Medicine

Richard H. McKee, Ph.D., Toxicologist, ExxonMobil Biomedical Sciences, Inc. and member Phthalates Ester Panel Toxicology Research Task Group

Tom Natan, Research Director, National Environmental Trust

Ruth A. Roberts, Ph.D., Toxicologist, Zeneca Central Toxicology Laboratory

Rachel Weintraub, Consumer Advocate, U.S. Public Interest Research Group

Gary M. Williams, M.D., Professor, Department of Pathology, New York Medical College

TAB E

Report to the
U.S. Consumer Product Safety Commission
by the

CHRONIC HAZARD ADVISORY PANEL
ON DIISONONYL PHTHALATE (DINP)

June 2001

U.S. Consumer Product Safety Commission
Directorate for Health Sciences
Bethesda, MD 20814



I. EXECUTIVE SUMMARY

Diisononyl Phthalate (DINP) is a complex of branched C-9 isomers that is used as a general purpose plasticizer to render polyvinyl chloride (PVC) flexible. It has a broad range of applications in toy manufacturing, construction, and general consumer product markets.

The Consumer Product Safety Commission convened a panel of scientific experts to determine whether DINP in consumer products poses a chronic hazard and, if feasible, indicate the probable harm to human health resulting from exposures to DINP. This is the final report of that panel, the Chronic Hazard Advisory Panel (CHAP) on Diisononyl Phthalate (DINP). On any particular issue, a range of viewpoints was held among panel members. This document reports the majority view for each issue, which typically was not unanimous.

Human exposure to DINP may occur via oral, dermal, and inhalation exposure routes. Based upon the physicochemical characteristics of DINP and limited monitoring data, general environmental exposure to DINP in the U.S. adult population is likely to be substantially lower than exposure to DEHP, which is estimated at $0.003\text{-}0.03\text{ mg kg}^{-1}\text{d}^{-1}$ (milligrams per kilogram body weight per day). The most significant exposures to DINP are likely to occur from the use of consumer items that consist of flexible plastic plasticized using DINP. These consumer items currently include PVC toys routinely mouthed by young children. Mouthing of DINP-containing toys may result in ingestion exposures of 0.07 and $0.28\text{ mg kg}^{-1}\text{d}^{-1}$ in reasonably highly exposed subsets of children 19-36 months old and 0-18 months old, respectively. Dermal uptake of DINP may also occur through prolonged contact of DINP containing products with skin or mouth. However, detailed data on the prevalence of DINP in consumer products that are in sustained contact with skin, such as sandals and rainwear, are not available, and there is fundamental uncertainty concerning the magnitude of dermal DINP uptake. Therefore, estimation of potential dermal exposure from such products remains speculative.

DINP belongs to a class of structurally diverse chemicals called peroxisome proliferators. These chemicals interact with a cellular receptor involved in lipid metabolism (i.e., peroxisome proliferator-activated receptor- α) to induce the proliferation of peroxisomes in addition to other cellular responses. Because rodents and humans differ in responses resulting from the activation of this receptor, a critical issue for the evaluation of rodent toxicity studies to predict human risk is whether the receptor is involved. The non-cancer toxicities discussed below are not believed to involve activation of this receptor.

Of the systemic effects from chronic exposure to DINP, spongiosis hepatitis, a degenerative lesion of the liver, is the most sensitive endpoint. The no observed adverse effect levels (NOAELs) identified in laboratory animals exposed to DINP were $15\text{ mg kg}^{-1}\text{d}^{-1}$ in one study and $88\text{ mg kg}^{-1}\text{d}^{-1}$ in a second study.

No human data were located on the reproductive or developmental toxicity associated with DINP exposure, therefore, the evaluation of these endpoints has relied upon animal studies. Using standard assays of prenatal oral exposure of rats to DINP, developmental toxicity consisting of renal and skeletal abnormalities occurred with NOAELs of 100 and 200 mg kg⁻¹d⁻¹ in the two standard prenatal developmental studies in rats. A two-generation study in the rat suggested an adverse effect upon pup weight gain with a lowest observed adverse effect level (LOAEL) of 250 mg kg⁻¹d⁻¹. In a recently published report of high dose exposure of rat dams to DINP during critical stages of fetal male reproductive tract development, male reproductive tract malformations consistent with an antiandrogenic effect were observed. Because of the large margin between doses to pregnant women and those expected to be without effect in the animal assays, the risk to reproductive and developmental processes in humans due to DINP exposure is extremely low or non-existent.

Collectively, the majority of data indicate that DINP is non-genotoxic, consistent with results obtained for other peroxisome proliferators. DINP has been tested in bacterial mutation assays and mammalian gene mutation assays *in vitro*, with or without metabolic activation, and found to be non-mutagenic. DINP has also been evaluated in both *in vivo* and *in vitro* cytogenetic assays with results supporting the idea that DINP is not genotoxic. Lastly, *in vitro* analysis of unscheduled DNA synthesis in rat hepatocytes which are known target cells of peroxisome proliferators provided no evidence of mutagenicity caused by DINP. Still, the peroxisome proliferation that results in rodents from receptor activation following DINP exposure may cause gene damage by increasing the level of hydrogen peroxide in the cell.

DINP is clearly carcinogenic to the rodent, inducing hepatocellular carcinoma in rats and mice of both sexes, renal tubular carcinoma in male rats, and mononuclear cell leukemia in male and female rats. Because nearly all male Fischer rats develop testicular interstitial cell tumors, the technical grade DINP studies in Fischer rats provide no information on the potential for development of these tumors. The chemical has not been tested for carcinogenicity in young rodents, an important limitation given that infants and toddlers are the ones most exposed to DINP. Chronic carcinogenicity studies have not been conducted in non-rodent species. Because of the lack of confidence in the relevance of the DINP rodent studies to humans, studies in species believed to produce results of greater relevance are clearly needed.

Peroxisome proliferators are a structurally diverse group of non-mutagenic chemicals that induce predictable pleiotropic responses including the development of liver tumors in rats and mice. These nonmutagenic chemicals interact variably with peroxisome proliferator-activated receptors (PPARs), which are members of the nuclear receptor superfamily. Evidence derived from PPAR α gene disruption indicates that of the three PPAR isotypes (α , β/δ , and γ), the isoform PPAR α is essential for the pleiotropic responses induced by peroxisome proliferators including the development of hepatocellular carcinomas. While the evidence is overwhelming that events downstream of PPAR α activation lead to liver cancer in rodents, the relative roles of the possible, nonexclusive, downstream mechanisms – oxidative stress, apoptosis, and cell proliferation, with or without Kupffer

cell involvement – are unclear. DINP is classifiable as a hepatic peroxisome proliferator and in that regard the liver tumors developing in rats and mice chronically exposed to DINP can be mechanistically related to PPAR α activation. The PPAR α -mediated mechanism of hepatocarcinogenesis is pronounced in rodents, but believed not readily induced in humans, especially at the doses resulting from current use of consumer products. The human risk was therefore seen as negligible or non-existent. The male rat α 2 μ -globulin mechanism of action for the production of rat kidney tumors has been postulated. Criteria for supporting an α 2 μ -globulin mechanism of action were applied and found to be met. The renal tumors in male rats at the high dose of DINP were therefore treated as rat specific and were not used to predict human risk. The mononuclear cell leukemia (MCL) in Fischer 344 (F344) rats was viewed of questionable significance and was not used in human risk prediction.

The available data indicate that humans do not receive DINP doses from current uses of DINP-containing consumer products that are associated with a significant increase in cancer risk. The most sensitive toxicity endpoint is spongiosis hepatitis, observed in male F344 rats. A Benchmark Dose (BD₀₅) estimate of 12 mg kg⁻¹d⁻¹ has been calculated. The corresponding acceptable daily intake (ADI) would be 0.120 mg kg⁻¹d⁻¹ based upon the application of a 100-fold combined uncertainty/adjustment factor. Background exposures to DINP and other phthalates could not be considered due to scientific uncertainties (see Section XI). One of the two estimates of plausible upper-bound DINP exposure is greater than the recommended ADI of 0.12 mg kg⁻¹d⁻¹. Namely, the estimate of 0.28 mg kg⁻¹d⁻¹ for ingested DINP among any children 0-18 months old who mouth PVC plastic toys containing DINP for 3 hours/day exceeds the recommended ADI. This implies that there may be a DINP risk for any young children who routinely mouth DINP-plasticized toys for 75 minutes/day or more. For the majority of children, the exposure to DINP from DINP containing toys would be expected to pose a minimal to non-existent risk of injury.

The exposure estimates addressed oral exposures only. Dermal exposure is expected from products plasticized with DINP in prolonged contact with external skin or oral mucosa; however the magnitude of this exposure is uncertain. The CHAP recommends experiments be undertaken to reduce this important source of uncertainty in the risk characterization.

The CHAP is conveying these findings in the series of questions and answers provided below. As noted above, the answers to the questions represent a majority view of the CHAP and are not necessarily the view of every member of the CHAP.

1. What is the critical endpoint to use to determine the ADI?

The critical endpoint is spongiosis hepatitis in male F344 rats.

2. What is the Acceptable Daily Intake (ADI) for DINP?

The ADI based on a BD_{05} and a 100-fold combined uncertainty/adjustment factor would be $0.120 \text{ mg kg}^{-1}\text{d}^{-1}$.

3. Are the results of the carcinogenicity bioassays on DINP adequate and sufficient to conclude that DINP is a rodent carcinogen?

Yes, DINP is clearly carcinogenic to the rodent, inducing hepatocellular carcinoma in rats and mice of both sexes and mononuclear cell leukemia in male and female rats. There is limited evidence of carcinogenicity based upon renal tubular carcinoma in male rats.

4. Is the carcinogenicity of DINP in rodents relevant to a determination of carcinogenicity in humans?

The hepatocarcinogenicity of DINP in rodents may be relevant to a determination of carcinogenicity in humans. Renal tubular carcinoma does not appear to be relevant to a determination of carcinogenicity of DINP in humans. Mononuclear cell leukemia is of unclear relevance for a determination of carcinogenicity of DINP in humans. See #6 for a further explanation.

5. Is DINP genotoxic?

The majority of data indicate that DINP is non-genotoxic, consistent with results obtained from analysis of other chemicals which function similarly to cause liver cancer in rodents through peroxisome proliferator-activated receptor- α (PPAR α). The peroxisome proliferation that results in rodents from receptor activation following DINP exposure may cause gene damage by increasing the level of hydrogen peroxide in the cell.

6. What is the mechanism by which DINP causes cancer in rodents and what is the relevance of such data to a determination of human risk?

DINP appears to induce liver cancer in rodents by a PPAR α -mediated mechanism that is pronounced in rodents, but believed not readily induced in humans under current exposure conditions involving consumer products. The human risk was therefore seen as negligible.

DINP appears to act by an $\alpha_2\mu$ -globulin mechanism to cause renal tubular carcinoma. The CHAP considers this to be a rodent specific mechanism and unlikely to be relevant to a determination of human risk. Mononuclear cell leukemia also may be a rodent-specific cancer of unclear relevance to a determination of human risk.

7. What is the carcinogenic risk to humans from exposure to DINP in consumer products?

The CHAP concludes that humans do not currently receive DINP doses from DINP-containing consumer products that are plausibly associated with a significant increase in cancer risk.

8. Is DINP a developmental or reproductive toxicant and would the exposures from consumer products result in developmental or reproductive risks?

Studies in rats at a high dose indicate an adverse effect on pup weight gain and male reproductive tract malformations consistent with an antiandrogenic effect. However, because of the large margin between doses to pregnant women and those expected to be without effect in the animal assays, the risk to reproductive and developmental processes in humans due to DINP exposure is extremely low or non-existent.

9. Is there evidence that children are more sensitive to the effects of DINP and if so how should that be incorporated into any risk determination?

No data are available on the effect of DINP on children or immature experimental animals, nor are there data that indicate that immature animals are more sensitive to causes of spongiosis hepatitis, the critical endpoint used by the Panel in the DINP risk assessment.

10. How should background levels of DINP and other phthalates be incorporated into a determination of risk?

There are no data on the interaction or additivity of dialkyl phthalate-induced toxic effects. Even if they act through a common mechanism, DAP effects are not necessarily additive, although the assumption of additivity for low exposure levels is a generally accepted conservative approach to addressing this source of uncertainty, as well as one that has theoretical support in the case that damage occurs by statistically independent increments.

However, because of the difficulty in developing reliable estimates of phthalate exposure for the population of interest (infants and toddlers) and uncertainties on how exposure estimates should be combined for comparison with the ADI, further explicit consideration of environmental background DAP exposures is not undertaken.

11. What conclusions, if any, can be reached about the skin penetration of DINP as a result of dermal contact? Should potential risks from dermal exposures be evaluated in the same manner as those from oral exposure?

Dermal uptake of DINP may occur through prolonged contact of DINP containing products with skin or mouth. However, detailed data on the prevalence of DINP in consumer products that are in sustained contact with skin, such as sandals and rainwear, are not available, and there is fundamental uncertainty concerning the magnitude of dermal DINP uptake. Therefore, estimation of potential dermal exposure from such products remains speculative.

12. Is the available exposure information adequate to permit the Panel to estimate the probable harm, if any, to human health that will result from exposure to DINP from the "reasonable and foreseeable" use of consumer products?

Estimated DINP exposures to children through toys and/or bedding/shoes/clothing, and to adults from shoes/clothing, are preliminary at best. Recognizing the limitations of the data, nevertheless, a prediction about the potential oral exposure to children under the age of three to certain consumer products can be made. Exposure information is inadequate to make predictions about dermal exposure.

13. If such an estimate were made, what methodologies were used in estimating the magnitude of the risk and what was the rationale for adopting that methodology?

A safety factor approach was applied to a non-cancer endpoint. To induce liver cancer, DINP acts by a PPAR α mechanism that is pronounced in rodents and that is not readily induced in humans under current exposure conditions. Thus, the human risk from cancer was seen as insignificant.

14. What are the uncertainties attendant with determining the risk to children from exposure to DINP in consumer products?

There are uncertainties associated both with the determination of exposure and the determination of hazard. Those associated with exposure include:

- lack of knowledge about what portion of toys contain DINP
- lack of knowledge about what other consumer products contain DINP
- lack of knowledge about how much DINP migrates out of toys and other consumer products
- uncertainties about how much time each day a child spends with toys and other DINP containing objects in their mouths
- lack of knowledge about how much, if any, DINP would be dermally absorbed

The uncertainties associated with the hazard include:

- the degree to which spongiosis hepatitis in rodents is relevant to humans
- how to extrapolate an effect from a lifetime exposure in rodents to a two-to-three year exposure in young children
- lack of knowledge of effects of early in life exposures; there are no toxicological data for exposures corresponding to infancy and toddler years
- lack of knowledge of effects in non-rodents; there are no chronic studies in non-rodent mammals
- lack of knowledge of PPAR α expression and related responses in the young; there are no data in human infants and children and scant data in non-human species
- lack of knowledge on mechanisms by which PPAR α induces rodent liver tumors

15. What is the risk to children from the oral exposure to DINP?

One of the two estimates of plausible upper-bound DINP exposure listed in Table IV-7 (Section IV) is greater than the ADI of $0.12 \text{ mg kg}^{-1} \text{ d}^{-1}$ recommended above for DINP. Namely, the estimate of $0.28 \text{ mg kg}^{-1} \text{ d}^{-1}$ for ingested DINP among any children 0-18 months old who mouth PVC plastic toys containing DINP for 3 hours/day exceeds the recommended ADI. This implies that there may be a risk of health effects from DINP exposure for any young children who routinely mouth DINP-plasticized toys for 75 minutes/day or more. For the majority of children, the exposure to DINP from DINP containing toys would be expected to pose a minimal to non-existent risk of injury. Further research addressing topics listed above (see question #14) could reduce the uncertainty associated with this characterization of DINP risk from consumer products.

TAB F



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: June 14, 2002

TO : Marilyn Wind, Ph.D.
Phthalates Project Manager

THROUGH: Hugh M. McLaurin, AED Engineering Sciences *Hmm*
Robert B. Ochsman, Ph.D., Human Factors Division Director *BO*

FROM : Celestine T. Kiss, M.A. Engineering Psychologist *CTK*
Division of Human Factors

SUBJECT : A Mouthing Observation Study of Children Under 6 Years

Attached to this memo is the Human Factors report for the phthalates project.

A Mouthing Observation Study of Children Under 6 Years of Age

**Celestine T. Kiss, M.A.
Division of Human Factors
U.S. Consumer Product Safety Commission
November, 2001**

EXECUTIVE SUMMARY

The U.S. Consumer Product Safety Commission (CPSC) staff has been investigating the potential health risks to children under three years of age from teething, rattles, and toys made from polyvinyl chloride (PVC) containing various dialkyl phthalate (DAP) plasticizers, especially diisononyl phthalate (DINP). Manufacturers use plasticizers such as DINP to soften the PVC to enhance the mouthing/teething qualities of the product.

In order to better understand children's potential exposure to DINP through mouthing, the CPSC undertook this extensive observational exposure study. The study was designed to obtain a broad range of data from which to better define the amount of time children mouth all products including those that could contain phthalates.

The subjects were recruited by Random Digit Dialing and screened by a series of questions in order to get a representative sample of the United States population. The study was conducted in two phases. In Phase I, the mouthing behaviors of 491 children ages 0 through 81 months were observed and recorded by their parent/legal guardian. In Phase II, trained personnel observed a total of 169 children ages 3 through 36 months. Of the 169 children in Phase II, 109 had participated in Phase I.

For all objects except pacifiers, estimated average daily mouthing times were 70 minutes (95% confidence interval 60-80 minutes) for children between 3 months and 1 year of age, 48 minutes (40-57 minutes) for children between 1 year and 2 years, and 37 minutes (27-39 minutes) for children between 2 and 3 years of age.

All soft plastic items, excluding pacifiers, which are items that could contain DINP, represent less than five minutes of mouthing time for the daily average mouthing times for each age group. Focusing on soft plastic toys, the youngest children averaged 1.3 minutes (.7 - 2.0 minutes), the 1-2 year olds averaged 1.9 minutes (1.2 - 2.6 minutes), while the oldest children averaged 0.8 minutes (.3 - 1.6 minutes) daily.

This study was undertaken to estimate children's exposure to phthalates as a result of mouthing soft plastic toys, such as teethingers and rattles. The CPSC's 1998 risk assessment estimated potential daily exposure based on mouthing behavior of a geometric mean of 12 minutes for 3 -12 month olds and 2 minutes for 13-26 month olds for teethingers, rattles, and toys. Based on these data CPSC concluded that few, if any, children were at risk from liver or other organ toxicity from the release of DINP from soft plastic toys. These new data establish that for soft plastic toys, the daily average mouthing times were 1.3 minutes for children between 3 months and 1 year, 1.9 minutes for children between 1 and 2 years and 0.8 minutes for children between 2 and 3 years of age. These new data are much lower than earlier estimates and show an even smaller risk of exposure to DINP for children mouthing and chewing soft plastic toys.

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Introduction

The U.S. Consumer Product Safety Commission (CPSC) staff has been investigating the potential health risks to children under three years of age from teething, rattles, and toys made from polyvinyl chloride (PVC) containing various dialkyl phthalate (DAP) plasticizers, especially diisononyl phthalate (DINP). Manufacturers use plasticizers such as DINP to soften the PVC to enhance the mouthing/teething qualities of the product.

The potential for DINP to cause toxic effects in children depends on the amount of DINP that is released from a product when it is mouthed or chewed and the amount of time a child spends with that product in his or her mouth. In December 1998, CPSC staff released the results of a study of the risks associated with DINP in children's products.¹ Based on the best information available at that time, the staff concluded that few, if any, children are at risk of liver or other organ toxicity from mouthing PVC toys that contain DINP. This conclusion was based on estimates of the amount of DINP ingested, which indicated that DINP exposure was at a level below the acceptable daily intake (ADI).² However, the staff identified a number of uncertainties in this assessment, particularly regarding the types of toys that children were mouthing, how long these toys typically are kept in their mouths, the migration of DINP from PVC, and the health effects of DINP. At the request of CPSC, manufacturers voluntarily removed DINP from products intended to be mouthed (teethers and rattles), but continue to use DINP in other soft toys.

The staff also recommended the following additional work:

- Convene a Chronic Hazard Advisory Panel (CHAP) of independent scientists to study issues related to chronic toxicity, including the risk of cancer, associated with exposure to DINP in children's PVC products.
- Conduct an extensive observational 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 less than 3 years of age that contain DINP.

The Commission convened a Chronic Hazard Advisory Panel of experts on DINP in December of 1998. The mission of the CHAP was to determine whether DINP is a carcinogen, mutagen, or teratogen or poses some other chronic hazard and, if feasible, estimate the probable

¹ CPSC (1998), *The Risk of Chronic Toxicity Associated with Exposure to Diisononyl Phthalate (DINP) in Children's Products*. U.S. Consumer Product Safety Commission, Bethesda, MD.

² The ADI is an estimate of the amount of a chemical a person can be exposed to on a daily basis for a lifetime with a negligible risk of harm.

harm to human health that would result from exposure to DINP. In its final report, the CHAP concluded the following:³

- Children may be exposed to DINP when they mouth PVC toys. Mouthing of DINP-containing toys may result in ingestion exposures of 0.07 and 0.28 milligrams of DINP per kilogram of body weight per day (mg/kg-d) in reasonably highly exposed subsets of children 19-36 months old and 0-18 months old, respectively.
- The available data indicate that humans do not receive DINP doses from current uses of DINP-containing consumer products that are associated with a significant increase in cancer risk.
- The CHAP calculated an acceptable daily intake (ADI) of 0.12 mg/kg-d.
- Children who routinely mouth DINP-plasticized toys for 75 minutes/day or more would exceed the ADI.
- For the majority of children, the exposure to DINP from toys containing DINP would be expected to pose a minimal to non-existent risk of injury.

The Commission also undertook the extensive observational exposure study because there was limited quantitative data available about the objects children mouth and the frequency and duration of the mouthing behaviors. In two other observation studies, parents were asked to observe their child and record his/her mouthing behaviors. In one study, conducted by a Dutch Consensus Group, parents observed the mouthing behaviors of 42 children between 3 and 27 months of age.⁴ In this study, the Dutch parents recorded their child's mouthing behavior during ten 15-minute periods over 2 days in the home. The second study (Juberg, et. al.) collected data on 385 children between the ages of 0 and 36 months. For one segment of this study, the parents were instructed to observe their child for an entire day and to document each item mouthed and its time (in minutes) in and out of the child's mouth. In another segment of this study, parents were instructed to observe their child on 5 non-consecutive days and record their mouthing behaviors.⁵ In both of these studies, the results indicated that the youngest children perform mouthing behaviors more often and for a longer total time than older children. However, CPSC staff questioned the accuracy of the results because the parents were recording the results to the nearest minute and based on CPSC data, the duration of mouthing behaviors were frequently only seconds, not minutes. In addition, in both of these non-CPSC studies, the subjects were convenience samples; that is, the subjects lived near the experimenters and were not necessarily representative of the whole population.

In 1998, CPSC staff conducted an observation study that did not involve parent observers. Eighty children, 1 to 8 years old, in daycare and school settings were observed. CPSC staff observed the children for four 30-minute segments over at least two days. These children exhibited a median mouthing frequency of 37 behaviors during 2 hours of observations,

³ CPSC (2001), *Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP)*. U.S. Consumer Product Safety Commission, Bethesda, MD

⁴ Groot, ME, Lekkerkerk, MC, and Steenbekkers, LPA, (1998). *Mouthing Behavior of Young Children: An Observational Study*. Wageningen Agricultural University, Household and Consumer Studies. Wageningen, The Netherlands.

⁵ Juberg, DR, Alfano, K, Coughlin, RJ, and Thompson, KM, (2001). "An Observational Study of Object Mouthing Behavior by Young Children," *Pediatrics* 107, 1, pp 135-141.

with observed frequencies ranging from 2 to 209 behaviors. The median total mouthing time for all objects was estimated to be nearly 3.5 minutes during the 2 hours of observations, with each child's time ranging from several seconds to over 35 minutes.⁶

New Observation Study

Objectives

There were two objectives for this new CPSC study. The first was to quantify the cumulative time per day that young children spend mouthing objects, including toys and other children's products and to specifically identify the objects that were being mouthed. The second was to determine if mouthing behaviors of children 36 through 72 months of age are substantial enough to merit an observation study with trained observers. Based on the results from the Dutch study, the Juberg study, and the previous CPSC staff study, CPSC staff expected mouthing behaviors to decrease with age.

Study Plan

After receiving approval from The Office of Management and Budget, this study was conducted from December 1999 through February 2001 in two phases in two geographical areas – Houston, Texas and Chicago, Illinois. The two geographical areas were selected to ensure that the subjects were reasonably representative of the population with regard to race, income, type of childcare, and gender. Both of these areas have large populations and large sub-populations in racial and income groups and in different types of childcare.

Phase I – Parent/Legal Guardian Observations

In this phase of the study, the parent/legal guardian observed the subject child and recorded all mouthing behaviors for four 15-minute segments over two days. They recorded the frequency and the length of time to the nearest second of all mouthing activities. The parent/guardian was provided with data entry sheets on which to record their observations and instructions on how to fill them out. Approximately two weeks later the contractor telephoned the parent/legal guardian to collect the mouthing data. If the subject child was under 36 months of age, the parent/legal guardian was recruited to participate in Phase II.

Phase II – Trained Observers Observations

Phase II of the study was conducted between January 2000 and February 2001. It involved a trained observer recording the subject child's behavior for a total of four hours on at least two different days. The observer conducted the observations at different times of the day, and if the child attended a child care facility outside of the home, attempts were made to observe the child there. The observer did not introduce anything new to the setting(s), except himself or

⁶ Smith, TP, and Kiss, CT, (1998), "Empirical Observations of Children's Mouthing Behaviors: Baseline Frequencies and Durations." U.S. Consumer Product Safety Commission, Bethesda, MD.

herself. The observer did not communicate with the child aside from that necessary for initial habituation and short responses when addressed so as not to offend the child.

Subjects

In Phase I, the mouthing behavior of 491 children ages 0 through 81 months was observed and recorded by their parent/legal guardian. In Phase II, trained observers observed a total of 169 children ages 3 through 36 months. Of the 169 children in Phase II, 109 participated in Phase I. The table below provides a breakdown of the Phase I and II subjects by age and geographical area.

Table 1.
Number of children involved in study by age, location, and phase.

Ages	Chicago, IL		Houston, TX		TOTALS	
	Phase I	Phase II	Phase I	Phase II	Phase I	Phase II
3 – 12 months	31	31	25	23	56	54
12 – 24 months	53	37	23	29	76	66
24 – 36 months	51	27	26	16	77	43
36 – 81 months	175	2	107	4	282	6
TOTALS	310	97	181	72	491	169

Note: the left age endpoint is not included in the group.

Observers

The observers in Phase II of the study participated in a two-day training session conducted by a CPSC staff member or by contractor staff. ITS RAM (also known as RAM Consulting) was contracted to conduct the observations. The observers were all trained using the same materials. At the end of the training sessions, all observers were administered an observation test, which they had to pass with a minimum score of 90% in order to participate in the study. The test consisted of watching two 30-minute segments of a videotape of two different children and documenting their behavior as if they were observing the children in person. The test results were compared to the baseline results established by CPSC staff and then compared to the median results from other individuals for reliability.

A total of 46 potential observers were trained during the course of the project. Of the 46, 10 people failed to meet the minimum 90% passing grade. Of the remaining 36, 18 individuals conducted observations; 4 individuals completed 67% of the observations.

Method

Phase I

The CPSC contracted with ORC Macro to recruit the subjects using telephone Random Digit Dialing techniques. When a household was contacted, the caller was asked a series of screening questions to determine if a child in the home met the age criteria. If an appropriate child was identified, the parent/legal guardian was asked to participate in the study. If they agreed, they were asked another series of questions about their child, the child's toys, daycare arrangements and family demographics (i.e., race, income, and education). Then they were asked to participate further by observing their child for Phase I (the parent observations). They were mailed a package containing instructions on how to observe and record their child's mouthing behaviors. Two weeks after the package was mailed to them, the contractor contacted them again to collect the observational data from them over the phone.

This protocol was revised about two thirds of the way through the study. While monitoring the number of children recruited for professional observations, staff became concerned that the parental observation and the long second contact questionnaire might have increased the chance of dropouts. As a result, the second contact was eliminated. In this phase of the study, 60 children were recruited for the observational study without either exposure time information or parentally observed mouthing times.

See Appendix A for Macro's report on how they recruited subjects and collected the data for Phase I.

Phase II

The observer contacted the potential subject's guardian by telephone. The observer identified him/herself by name and explained that he/she was representing RAM Consulting and the CPSC. The subject's guardian was given more information about the study (e.g. why it was being conducted, how the study was organized, monetary compensation for participation, etc.). If the subject's parent/guardian was still interested in their child participating in the study, a time and date were agreed upon between the family and the observer to have an orientation followed by session one of the observations of the subject.

On the appropriate date and time, the observer arrived at the designated location to conduct the orientation and begin session one of the observations. The first 15-30 minutes of the first session were spent getting to know each other, visiting, looking around the location, and allowing the child to get comfortable with the observer. During this time, the guardian filled out the necessary paperwork about the child's normal routine of waking, sleeping, and eating times, daycare time and location, and favorite toys. This meeting familiarized the parent(s) and child with the observer, and helped decrease the potential for behavioral artifacts during the actual observations.

After the 15-30 minutes of orientation, the actual observation session began. For purposes of this study, mouthing was defined by the researchers as any behavior in which an item came into contact with the observed child's lips, tongue, or inside of the mouth for any length of time. The item being mouthed was identified as precisely as possible by the observer. The observer did not provide the subject with any new items and did not prevent the subject from mouthing anything. The subject's parent/guardian was present during the observation sessions and they were advised to care for the subject as if the observer was not present. So, if the parent/guardian did not want the subject mouthing an item, they were free to remove the item. The observer used a stopwatch and data collection sheets to record the duration, item mouthed, and type of mouthing behavior. The type of mouthing referred to whether the child chewed, sucked or bit on the item. The stopwatch used stored the duration of each separate mouthing event so the observer did not have to take his/her eyes off the child to write down the times the item went in and came out of the child's mouth. At the end of the observation time, the observer was able to retrieve all the mouthing times from the stopwatch and record them on the data sheet. The observers were instructed not to observe during meals, but if the subject had a snack during the observation that information was recorded.

Each observation session consisted of six half-hour segments, for a total of three hours per session. During each half hour observation period, the observer spent the first ten minutes writing general notes or a summary regarding the subject's environment (e.g. room of the home/day care, indoors or outdoors, toys present, caregiver present and so forth). The following 20 minutes were spent recording the observations of all items that the child put into his/her mouth, as well as the duration and type of mouthing involved. At the end of each half-hour segment or at the end of the three hours (whichever was least disruptive to the child's routine), the observer located each of the items that had been mouthed and recorded a more detailed description of the item than originally had been documented during the active session. At the end of the session, the observer set the date and time of the second three-hour observation session.

The second observation session was performed exactly as the first observation session. However, observations began immediately after the observer arrived, and at the conclusion, the observer thanked the subject and his/her guardian and explained that the family's payment for their participation would be mailed to them. Due to difficulty recruiting participants, the incentive was raised from \$100 to \$150 later in the study.

Demographics

For the entire sample 55 percent were boys and 45 percent girls. With respect to household size, 68 percent of children lived in households where they were the only child who was six years old or younger, 27 percent had a sibling six or younger and 4 percent of the children had two or more siblings six or younger. With respect to marital status, 83 percent of adult parents or guardians identified themselves as married, while 17 percent were divorced, widowed, unmarried, separated, etc. Sixty one percent of the children were from the Chicago area and 39 percent from Houston. Racial composition of children and adults in the sample are shown in table 2 below.