UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Ballot Vote Sheet

CPSC/OFFICE OF
THE SECRETARY

2000 MAY 19 A 11:39

Date: May 18, 2000

TO : The Commission
Sadye E. Dunn, Secretary

FROM : Michael S. Solender, General Counsel MSS
Harleigh Ewell, Attorney, GCRA (ext. 2217) HE

SUBJECT : Federal Register Notice Announcing the Second Meeting of the Chronic Hazard Advisory Panel on DINP

BALLOT VOTE DUE: May 23, 2000.

The second meeting of the Chronic Hazard Advisory Panel (CHAP) on Diisononyl Phthalate (DINP) is scheduled for June 20-22, 2000. On June 20, there will be an opportunity for submission to the CHAP of oral comments from the public. The meetings on June 21-22 will be for the CHAP members to continue to discuss issues and the report they will be writing. The attached draft Federal Register notice would announce the meeting.

Please indicate your vote on the following options.

I. APPROVE THE ATTACHED FEDERAL REGISTER NOTICE AS DRAFTED.

(Signature) (Date)

NOTE: This document has not been reviewed or a[illegible] Commission.
Initial SD Date 5/19/00

CPSA 6 (b)(1) Cleared
5/19/00
No Mfrs/Prvtlbls or Products Identified

II APPROVE THE ATTACHED FEDERAL REGISTER NOTICE WITH CHANGES (please specify).

_____ _____
(Signature) (Date)

III. TAKE OTHER ACTION (please specify).

_____ _____
(Signature) (Date)

Attachment

Comments/Instructions:

Billing Code 6355-01

CONSUMER PRODUCT SAFETY COMMISSION

Notice of Meeting of Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP) and Opportunity for Public Comment

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of meeting

SUMMARY: The Commission announces the second meeting of the Chronic Hazard Advisory Panel (CHAP) on diisononyl phthalate (DINP). The Commission appointed this CHAP to advise the Commission on any chronic hazards of cancer, birth defects, and gene mutations associated with children's products containing DINP. The public may submit written or oral comments on the issues to be considered by the CHAP.

DATES: The opportunity for the presentation of oral comments will be on June 20 from 10 am to 5 pm. The remainder of the meeting will be held from 8·30 am to 5:00 pm on June 21 and from 8:30 am to 4:00 pm on June 22, 2000.

Requests to present oral comments, and a written copy of the text of the oral comments, must be filed with the Office of the Secretary no later than June 13, 2000.

Written comments must be received no later than June 13, 2000

ADDRESSES: The meeting will be held in the fourth floor hearing room in the Commission's offices at 4330 East-West Highway, Bethesda, Maryland.

Written comments, or requests to present oral comments and the written text of such comments, should be mailed, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, D.C 20207-0001, or delivered to the Office of the Secretary, Consumer Product Safety Commission, Room 502, 4330 East-West Highway, Bethesda, Maryland, telephone (301) 504-0800. These items also may be filed by telefacsimile to (301)504-0127 or by email to *cpsc-os@cpsc.gov*. These items should be captioned "CHAP on DINP."

FOR FURTHER INFORMATION CONTACT: Concerning requests and procedures for oral presentations of comments· Rockelle Hammond, Docket Control and Communications Specialist, Consumer Product Safety Commission, Washington, DC 20207; telephone: (301) 504-0800 ext. 1232, email *cpsc-os@cpsc.gov*. For all other matters: Marilyn Wind, Directorate for Health Sciences, Consumer Product Safety Commission, Washington, D.C 20207, telephone (301) 504-0477, ext 1205; email *mwind@cpsc.gov*

SUPPLEMENTARY INFORMATION:

The Commission has been concerned with potential risks posed to children under 3 years of age by the plasticizer diisononyl phthalate (DINP), which is used to soften some

children's teethers, rattles, and toys made from polyvinyl chloride (PVC). DINP can leach from such products when they are mouthed or held by children, causing some DINP to be absorbed through skin and mucous membranes. DINP has been shown to cause liver and other organ toxicity in laboratory animals. Also, the Commission has received a petition (No HP 99-1) from the National Environmental Trust and eleven other organizations asking that the Commission ban PVC in children's products.

The Commission appointed a seven-member CHAP to evaluate the existing scientific information regarding the mechanism by which DINP may cause cancer and the implications of this on the potential cancer risk to children The CHAP members were selected from scientists recommended by the National Academy of Sciences. See 15 U.S.C. 2077, 2030(b). The first meeting of the CHAP was on May 10-11, 2000. The second meeting of the CHAP will be on June 20-22, 2000, in the fourth floor hearing room at the Commission's offices in Bethesda, MD (see address above).

The CHAP is seeking public comment on issues relating to the hazard, exposure, and risk posed by DINP in children's products It is interested in comments and data pertaining to: (a) what the appropriate Acceptable Daily Intake (ADI) of DINP would be; (b) which critical endpoint to use to determine the ADI, (c) the mechanism by which DINP causes cancer in rodents and the relevance of these induced

neoplasms to human risk; (d) the appropriate risk assessment model or models to determine human risk; (e) the differential sensitivity/susceptibility of young children to the effects of DINP, if any, and how to incorporate that into an assessment of risk; and (f) age-dependent pharmacokinetic differences In addition, it is particularly interested in the following.

1. Are Diisononyl Phthalate (DINP) rodent cancer bioassay data inapplicable to human hazard identification?

2. Is there convincing evidence that a linear extrapolation approach for risk assessment is not appropriate for DINP?

3. What is the most appropriate measure of the biologically effective dose for DINP-induced liver cancer?

4. Any data available on the percutaneous absorption of DINP. (Provide any data available on absorption of DINP from the oral mucosa)

5. Any available data on the pharmacokinetics of DINP including salivary metabolism.

6. Any available data on DINP metabolites.

7 Any available information on spongiosis hepatis.

8. Total exposure to phthalates in adults and children.

9. Toxicological interactions between phthalate esters

The CPSC would appreciate it if any suitable data are submitted in the form of an Excel Spread Sheet, a space delimited ASCII file, or a SAS (SD2 or SSD) dataset.

There will be an opportunity for oral comments on June 20, from 10 am to 5 pm. As explained at the beginning of this notice, persons wishing to present oral comments must file a request, and a written copy of the text of their comments, with the Commission's Office of the Secretary no later than June 13, 2000

Commenters should limit their presentations to approximately 15 minutes, exclusive of any periods of questioning by the members of the CHAP or the CPSC staff. The CHAP reserves the right to further limit the time for any presentation and to impose restrictions to avoid excessive duplication of presentations.

Interested persons may also file written comments with the CHAP. Written comments must be filed with the Office of the Secretary no later than June 13, 2000.

The remainder of the CHAP meeting will be from 8:30 am to 5:00 pm on June 21 and from 8.30 am to 4:00 pm on June

22, 2000 During this part of the meeting, the CHAP will discuss issues and the report it will write

Dated

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Sayde E. Dunn, Secretary
Consumer Product Safety Commission