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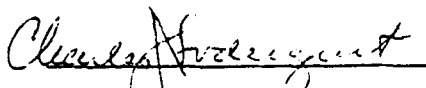
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STUDY REVIEW

PRESENCE OF CHEMICALS ASSOCIATED
WITH PVC/CPVC PLASTIC PIPE
IN POTABLE WATER

FOR
CALIFORNIA PIPE TRADES COUNCIL



CHARLES J. SODERQUIST, Ph.D.

SEPTEMBER 1980

BFG06904

SEP 27 1980

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SUMMARY OF REPORT

1. Chemical components of glues and primers used to install PVC and CPVC pipe have been found to leach into water contained in the pipe.
2. Regulatory agencies -- including the U.S. EPA and the California Department of Health Services -- have not established Maximum Contaminant Levels for these chemicals. The California Department of Health Services has proposed guidelines to estimate a Maximum Acceptable Level based on existing permissible occupational exposure levels (TLV's).
3. The Montgomery Consulting Engineers study for the Department of Health Services and plastic pipe manufacturers is deficient in that unrealistic pipe joint configurations and average gallon/day flow rates were used.
4. All four of the reviewed studies contained examples wherein levels of glue and primer components exceed the proposed California Department of Health Services Maximum Acceptable Levels in water. This is true for data from samples collected under continual use and initial occupancy conditions. These data should be carefully and cautiously interpreted.
5. It would appear that unless the new occupants reflush their plumbing system, they could be exposed to levels of contaminants up to 40 times the Maximum Allowable Concentrations during initial occupancy.

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INTRODUCTION

At the request of the California Pipe Trades Council, California Analytical Laboratories, Inc. has agreed to review pertinent documents as they apply to the potential hazards associated with the use of CPVC and PVC plastic pipe components for the transport of potable water.

These studies include:

- (1) "Plastic Pipes Study" of James M. Montgomery, Inc. completed for the California Department of Health Services and the plastic pipe and fitting manufacturers, August 1980.
- (2) Wang and Bricker Study (Bull. Environ. Contam. Toxicol., 23,620 (1979)).
- (3) California Analytical Laboratories, Inc. report dated May 15, 1980.
- (4) California Analytical Laboratories, Inc. report dated June 10, 1980.

BACKGROUND

Under the direction of Dr. Charles J. Soderquist, we have attempted to address the following points: (1) how scientifically valid are the studies which have been conducted; and (2) what extrapolations can be made and reasonable conclusions drawn from these studies, particularly the James M. Montgomery report, in conjunction with the known toxicological properties of the identified contaminants, to determine whether the levels found represent a health risk under normal water-use conditions.

The reviewed studies focus on the leaching of glue components from glued ("welded") PVC or CPVC joints. The leaching of vinyl chloride monomer from PVC (poly vinyl chloride) pipe is not at issue. Commerical glues and primers are known to contain ~~a mixture of two~~ or more of the following organic solvents: methylethyl ketone (MEK), tetrahydrofuran (THF), cyclohexanone (CYH), and dimethylformamide (DMF).

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TOXICOLOGY

The true health hazard of any chemical, man-made or natural, can not be assessed solely in terms of its toxicity, as established by acute (single, lethal dose) and chronic (low dose, long term) trials using laboratory animals. Other factors, including route of exposure (dermal, oral, inhalation), duration of exposure and the susceptibility of the person (age, health) must be considered. For example, while a large oral dose of the toxicant ethyl alcohol can be lethal to an adult, long term (chronic) exposure to low doses may result not in death, but liver deterioration. A comparable low level dose may, on the other hand, cause severe effects or death to a child or an unborn fetus. Substances which show carcinogenic potential are considered hazardous at any dosage (the Delaney law).

While regulatory agencies such as the Food and Drug Administration (FDA) have rigid protocols for establishing acceptable contamination levels ("residue" levels) for non-carcinogenic substances which have been intentionally added (as pesticides) to consumable crops, other agencies (e.g. U.S. Environmental Protection Agency [EPA]) must deal with unintentionally added substances for which appropriate toxicity and exposure data often do not exist. In the case of potable water,

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EPA has established Maximum Contaminant Levels for a select set of substances. Water which exceeds the limit for any single substance is considered non-potable. Only six organic chemicals are currently regulated. (See Table I below).

TABLE I
Maximum Contaminant Levels for
Organic Chemicals in Water

<u>Chemical</u>	<u>mg/L (ppm) allowed</u> <u>a/</u>
endrin	0.0002
lindane	0.004
methoxychlor	0.1
toxaphene	0.005
2,4-D	0.1
silvex	0.01

a/ California Department of Health Services, Title 22

The Occupational Safety and Health Administration (OSHA) has collected a large volume of data on the effects of chemicals, mainly organic solvents, on worker health. To protect the health of workers who are continually exposed to chemicals as a result of their occupation, levels of these chemicals in the workplace environment (air) are limited to certain maximum acceptable values, called Threshold Limit Values (TLV's).

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If a chemical (e.g. an organic solvent such as THF or DMF) is found as a contaminant in a potable water supply, the establishment of an acceptable (safe) level is more difficult. It is not generally possible to monitor the level of contaminant in water and correlate its effects over a long period of time in order to decide what level could be deemed safe--effects of low level exposure may take years to manifest as a chronic disease or disorder. The California Department of Health Services (CDHS) Hazard Alert System has adopted the policy that, in the absence of more directly applicable data, TLV's set by Cal/OSHA for workplace environments will be used to estimate safe levels in water. A flow chart of the arithmetic extrapolation procedure is attached. (Document #2). In brief, the procedure converts the TLV levels into drinking water levels by assuming an (arbitrary) safety factor of 100. That is, since CDHS does not know what a "safe" level of THF in water is, they must base their estimate on known effects (inhalation TLV's), extrapolate to exposure via ingestion (drinking water) and then only allow one-hundredth of that amount due to the uncertainties in their procedure. The calculation results--Maximum Acceptable Levels or MAC values--for dimethylformamide (DMF), methyl ethyl ketone (MEK), tetrahydrofuran (THF) and cyclohexanone (CYH) are summarized in Table II. Additional information relative to the toxicity of these four compounds is attached. (Attachment #9).

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TABLE II

Estimated Maximum Acceptable
Concentrations in Water

<u>Compound</u>	<u>TLV (mg/m³)</u> <u>a/</u>	<u>MAC (mg/L, ppm)</u> <u>b/</u>
DMF	30	0.30
MEK	590	6.0
THF	590	6.0
CYH	200	2.0

a/ Cal/OSHA

b/ Assumes 10 Kg child consuming 1 liter of water per day
and a lung retention factor of 1.0.

0.2 liter
/ 100 mg

0.20

PVC SOLVENT STUDIES

Study A. James M. Montgomery

Of the documents under question, the most exhaustive study completed to date is that of the James M. Montgomery group for the Hazard Alert System (CDHS, Berkeley) and for Hoge, Fenton, James and Appel, Inc., Attorneys at Law, who represent the PVC pipe manufacturers. (Attachment #1).

We have reviewed this report based on our experience with projects of this type and with the analytical methodologies employed. While the contractor appears to have done an adequate job in providing the data required by the experimental protocol, certain design and analytical deficiencies appear. These are addressed in three parts.

1. There is some question as to whether a controlled laboratory study is an appropriate mode of evaluation. Generally, a laboratory simulation of a "real-world" phenonema is carried out only when the "real-world" is not accessible. Examples of PVC/CPVC plumbing already do exist and could have been monitored-- monitoring certainly should be considered as a future goal.

*The last two sentences are open to argument.
For example - calculations v.s. actual measurement of
the strength of various pipe materials.*

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2. Our criticisms of the methodology are:

(a) Lack of data for the composition of the primers and glues limits the opportunity to compare the THF-MEK-CYH-DMF values for any particular study, and casts doubt on the validity of the entire experiment by opening the possibility that glues with low THF-MEK-CYH-DMF or different content were used.

While this data is apparently being collected by the contractor (see Attachment #1a), it is essential, in our view, to verify that the composition of the glues and primers used is typical of all glues commercially available. Glues containing twice the amount of THF would be expected to cause twice the level of leached THF in water.

(b) The "kinetic" study is of no use because: (1) contrary to what would be expected, levels of some contaminants decrease with time; and (2) use of an alternate pipe design (2", capped) and different brands of glue/primer preclude any comparison to the "static" and "usage" studies. It would have been helpful to be able to use the kinetic data to predict the contaminant levels in the "usage" test which would result from increased (greater than overnight) stagnation time.

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See Attachment #4

*more - better data
for lead analysis
to help in
determine cause
of lead contamination*

(c) Insufficient detail is provided concerning the determination of DMF, particularly the precision and accuracy of analysis. In our experience, this analysis is difficult and not reproducible. Considering that DMF is the most toxic of the four solvents, good analytical data for low levels of contamination are essential.

3. Our final criticism involves the experimental design of the "usage" study, which was intended to simulate consumer exposure to domestic, potable water potentially containing leached solvents. We feel that the design of the "usage" study insufficiently modeled typical plumbing and water use regimes and certainly did not adequately assess any "worst case" situations. The following specific criticisms apply:

*was accepted
in the C 772.
There was a lower
ratio, estimated
at 1.2--that is,*

(a) The ratio of feet of pipe to number of glued joints was 2.375. Typical 2-bath, 1400 square foot tract houses in Sacramento, California, have ratios near 1.2--that is, more glued joints and more glue per foot of pipe than was used in the study. (Attachment #4).

*dependence on water flow
350 - 450
gallons per day*

(b) The average gallon/day flow through the single system was 350, while 250 gallon/day appear to be more typical of total (i.e., multi-outlet)

family-of-four use (see Attachment #5). Lower flow rates (perhaps 50 gallon/day or less) would seem more typical for a single outlet.

(c) Most tap water consumption occurs at kitchen and bathroom faucets. Typical plumbing at a kitchen sink involves up to ten cemented joints (or more if accessories such as a dishwasher are used) in the four feet of pipe immediately preceeding the tap outlet, yielding a pipe foot-cemented joint ratio of 0.40, about six times as many glued joints per foot than that used in the study. Thus, it would be expected that the level of contaminants in the four feet of pipe preceeding an outlet would exceed those found in the James M. Montgomery study (usage test) by a factor of about six. Considering this factor alone, a consumer who samples (drinks) the initial 250 ml/flow of tap water might be exposed to levels about six times those found in the study.

(d) While the choice of a twelve hour (overnight) stagnation time may be appropriate to model daily use, there was no provision in the experimental design to assess prolonged dwell time typical of weekend absence (48 hour stagnation), seldom used outlets (? hour stagnation) or seldom used homes (condominiums, vacation homes).

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In summary, most of the data collected according to the established experimental design, the sampling and analytical methodologies, and the report formats appear scientifically valid. We do find, however, significant deficiencies in the design itself. The "usage" study data, and the "static" tests (Montgomery Tables 3-1 through 3-5, respectively) are reproduced below.

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STUDY

TABLE 3-1

METHYLETHYLEKETONE CONCENTRATION IN STATIC TEST SYSTEMS

AC 1. 6

Sample	System	Pipe/ Joints/ Water	Concentration (µg/l)					
			Static CPVC/ Good/ Hot Pasadena	Static CPVC/ Poor/ Hot Pasadena	Static CPVC/ Good/ Cold Pasadena	Static CPVC/ Poor/ Cold Pasadena	Static PVC/ Good/ Colorado River	Static PVC/ Good/ State Project
Raw Water	0		ND	ND	ND	ND	ND	ND
Flush	0		3,700	500	3,500	3,600	1,200	2,100
Two Weeks	336		69,000	75,000	69,000	115,000	57,000	92,000
24 Hrs	24		1,100	200	1,300	2,200	5,160	113
48 Hrs	24		197	61	553	697	1,167	197
120 Hrs	72		600	200	1,670	2,761	1,210	468
144 Hrs	24		75	23	325	577	830	655
146 Hrs	4		ND	5.5	166	168	NS	NS

ND = Not detected.
NS = Not sampled.



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Cable Address: Montgomery Pasadena California Telex: 67-5420

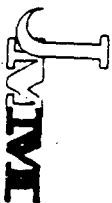
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And even

ND = Not detected
NS = Not sampled.

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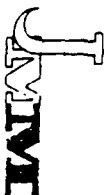
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TABLE 1-1

CYCLOHEXANONE CONCENTRATION IN STATIC TEST SYSTEMS

Sample	System	Dwell Time (hrs)	Concentration (µg/l)					
			Type/ Joint/ Water	Static CPVC/ Good/ Hot Pasadena	Static CPVC/ Poor/ Hot Pasadena	Static CPVC/ Good/ Cold Pasadena	Static CPVC/ Poor/ Cold Pasadena	Static PVC/ Good/ Colorado River
Raw Water		0		ND	ND	ND	ND	ND
Flush		336		200	200	200	200	54
Two Weeks		24		7,000	8,300	10,000	13,000	800
24 Hrs		24		100	100	100	200	8.2
48 Hrs		24		29	3.1	163	165	29
120 Hrs		72		200	300	213	323	99
144 Hrs		24		15	ND	81.5	88	ND
146 Hrs		4		ND	ND	19	21	NS

ND = Not detected.
NS = Not sampled.



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TABLE 3-4

N,N-DIMETHYLFORMAMIDE CONCENTRATION IN STATIC TEST SYSTEMS

/10/ 3.30

Sample	System	Dwell Time (hrs)	Concentration (ug/l)					
			Pipe/ Joints/ Water	Static CPVC/ Good/ Hot Pasadena	Static CPVC/ Poor/ Hot Pasadena	Static CPVC/ Good/ Cold Pasadena	Static CPVC/ Poor/ Cold Pasadena	Static PVC/ Good/ Colorado River
Raw Water				ND	ND	ND	ND	ND
Final		0		ND	ND	ND	ND	ND
Two Weeks		336		150	120	110	170	200
24 Hrs		24		ND	ND	ND	110	4,300
48 Hrs		24		ND	ND	ND	ND	140
120 Hrs		72		ND	ND	ND	ND	45
144 Hrs		24		ND	ND	ND	ND	ND
146 Hrs		1		ND	ND	ND	ND	60
				ND	ND	ND	ND	ND

ND = Not detected.
NS = Not sampled.



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TABLE 3-5

CONCENTRATIONS OF METHYLETHYLKETONE, TETRAHYDROFURAN,
CYCLOHEXANONE AND N,N-DIMETHYLFORMAMIDE IN CPVC SIMULATION
TEST SYSTEM

Sample	ACCL	Flush	CONCENTRATION (μg/l)						Day 30 Flowing	Day 10 Flowing	Day 5 Flowing	Day 1 Flowing	Day 30 Flowing
			Day 1 Stagnant	Day 5 Stagnant	Day 10 Stagnant	Day 30 Stagnant	Day 1 Flowing	Day 5 Flowing	Day 10 Flowing	Day 30 Flowing	Day 1 Flowing	Day 5 Flowing	Day 10 Flowing
Methylethylketone	ACCL	2400	100	2	227	28	86	9.4	3.7	3.0			
Tetrahydrofuran	CPVM	3300	300	2.4	879	55	264	31	20	10			
Cyclohexanone	CPVM	200	100	31	79	109	47	4	9.1	ND			
N,N-Dimethylformamide	CPVM	ND	ND	ND	ND	ND	ND	ND	ND	ND			

ND = NOT DETECTED



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Study B. Wang and Bricker

The work of Wang and Bricker (Attachment #6) showed that a plumbing system consisting of about 80 feet of 1.5 inch diameter PVC pipe, presumably plumbed in the usual fashion, continued to leach MEK and THF even after eight months of continual (40 gallons per day) use. Their Table I data is reproduced below.

Bull. Environm. Contam. Toxicol. 23,620-623 (1979)

2-Butanone and Tetrahydrofuran Contamination in the Water Supply¹

T. C. Wang and J. L. Bricker

Harbor Branch Foundation, Inc., RR 1, Box 196, Ft. Pierce, Fla. 33450

MEK (2-butanone) and THF (tetrahydrofuran) were found in high concentrations in our laboratory's water outlets 6 mo after PVC (polyvinyl chloride) pipe installation. Subsequent analysis confirmed that the solvents from the PVC pipe cement used to join the tubing were leaching into our water supply. Water samples were taken at various residence times in the pipe to observe the solvents' leaching kinetics.

TABLE 1. Concentration (ppm) of MEK and THF in Water Samples at Various Residence Times in the PVC Pipe

Residence Time (h)	Samples taken 6 mo after pipe installation		Samples taken 8 mo after pipe installation	
	MEK	THF	MEK	THF
0	0	0	0	0
4	0.4	1.0	0.1	0.7
8	0.6	1.7	-	-
16	1.8	5.8	0.6	2.4
24	2.2	8.9	1.1	3.7
48	3.9	12	2.1	6.8
64	4.5	13	-	-
72	-	-	2.2	7.5
96	4.5	13	-	-

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Study C. California Analytical Labs, Report, May 1980

This report (Attachment #7) consisted of results of sampling a new house in Lancaster, California, which had been partially plumbed with CPVC pipe. MEK, THF, and CYH were found at levels of up to 92 ppm. *WHEN*

Study D. California Analytical Labs Report, June 1980

Samples were collected from a newly plumbed CPVC system at Mercy Hospital, Sacramento, which apparently had never been flushed. MEK and THF were found at levels up to 240 ppm. (See Attachment #8).

WHEN

SUMMARY OF PVC SOLVENT STUDIES

THF and MEK were found in all four studies, and DMF was found in two of the four. This certainly indicates that leaching of glue components is a real phenomena. *True*

Consumer exposure to domestic water contaminated by transport through CPVC pipe should be assessed under two separate conditions. First, what exposure levels will result from continual, typical use conditions. Second, what exposure levels will result during the initial occupancy of the house. These situations are assessed below.

For the first case, we assume that the CPVC plumbing has been flushed and in use for some period of time.

The Montgomery "static" tests for THF indicate that levels in excess of the MAC values are obtained even after six flushes over 19 days of leaching. The Montgomery "usage" study, when corrected for a more typical pipe feet to cemented joint ratio as we propose (Table IV), yields concentrations very close to the MAC values after 10 days of use. Considering the other experimental design problems which we have pointed out (excessive flows, inadequate stagnation), these data should be interpreted as representing minimum levels to be expected

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TABLE IV

Recalculated J.M. Montgomery "Usage Study" Data

Contaminant	Flush	Concentration ($\mu\text{g/L}$, ppb) ^{a/}							
		Day 1 Stagnant	Day 5 Stagnant	Day 10 Stagnant	Day 30 Stagnant	Day 1 Flowing	Day 5 Flowing	Day 10 Flowing	Day 3 Flowing
MEK	14,000	600	12	1400	170	520	56	22	18
THF	20,000	1800	14	5300	330	1600	190	120	600
CYH	1,200	600	190	470	650	280	24	55	< 20
DMF	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60	< 60

Substrate: 4-fluorobenzonitrile, 4-phenyl-2-pyridone, 4-phenyl-2-py

MEK, THF, CYH, DMF, and other solvents were found in the water, and the concentration was found to be 10 joints/4 feet.

a/ Data of James M. Montgomery Study, Table 3-5, modified to reflect 10 joints/4 feet

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in a real-world situation. This observation is borne out by the other two relevant studies, which are based on samples taken from in-use PVC/CPVC systems, and yielded samples containing excessive levels of contaminants, particularly THF. Data from all three studies are summarized for comparison to the estimated MAC values obtained from the California Department of Health Services procedure (Table V).

For the second case, we assume that a CPVC system has been cured, pressure tested (1 - 2 days stagnation), flushed with up to three volumes of water, and then left unused for some period of time. For example, a contractor performs these steps, the dwelling is sold, and the new occupants move in two weeks after any water use has occurred. The Montgomery static test data (Tables 3-1 through 3-4) and the California Analytical Lab Report of June, 1980 represent this use pattern; data is reproduced in Table VI for comparison to the MAC values. It would appear that unless new occupants reflush their plumbing system, they could be exposed to levels of contaminants up to 40 times the Maximum Allowable Concentrations during initial occupancy.

*This paragraph is completed in cover
see letters from APAC and Payne.*

TABLE V
Comparison of MAC Values
To Selected Data From Solvent Studies

Part-Per- Million (mg/L) Found

Contaminant	Maximum Allowable Concentrate <u>a/</u>	Montgomery Studies			Wang & Bricker (96 hr.) <u>d/</u>	Calif. Analyt. <u>e/</u> May 1980
		Static <u>b/</u>	Usage, Modified <u>c/</u> 10-day Stagnant			
MEK	6.0	1.4	1.4	4.5	4.1	
THF	6.0	6.7	(5.3)	13	37	
CYH	2.0	0.26	0.47	N.A.	0.8	
DMF	0.30	N.D.	0.06	N.A.	< 5	

23.

Notes:

- a/ Calculated according to California Department of Health Services procedure. See text.
b/ Average of all four CPVC plumbing regimes at the "120 hr." sampling. See Montgomery Tables 3-1 through 3-4 which are reproduced in text.
c/ Montgomery usage test Table 3-5 "Day 10 Stagnant" data recalculated for 10 joint per 4 foot regime. See copy of Table 3-5 in text.
d/ See Wang and Bricker data as reproduced in text and attachment #6.
e/ See attachment #7.

N.D. = None detected

N.A. = Not analyzed

TABLE VI

Comparison of MAC Values to Peak Value
Data From Solvent Studies

Parts-Per-Million (mg/L) Found

<u>Contaminant</u>	<u>Maximum a/ Allowable Concentration</u>	<u>Montgomery Static Study b/ (2 Week Stagnation)</u>	<u>Calif. Analyt. June, 1980</u>
MEK	6.0	80	19
THF	6.0	240	250
CYH	2.0	9.6	< 5
DMF	0.30	0.14	Not Analyzed

Notes:

a/ Calculated according to California Department of Health Services procedure;
see text.

b/ Average of four CPVC plumbing regimes after an initial 3-volume flush
followed by two weeks of stagnation. See Montgomery Tables 3-1 through 3-4
in text.

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DOCUMENTS

1. James M. Montgomery, Consulting Engineers, Inc.
"Hazard Alert System, California Department of Health Services, Plastic Pipes Study, Draft Report"; August, 1980. A letter of August 29, 1980 from Kenneth Reich to Marc Lappe' accompanied.
2. Marc Lappe', California Department of Health Services/ Department of Industrial Relations -- Hazard Alert System letter to Mr. Ray Leonardini; May 22, 1980.
3. Beverlee A. Myers, California Department of Health Services letter to Mr. Donald Turner, Director of Housing and Community Development, Sacramento; January 28, 1980.
4. Plumbing plan for 2 bath house from Luppen and Hawley, Inc., Sacramento, California. Plan received from Mr. John Gorman, California Pipe Trades Council.
5. Tom Johnson, Department of Housing and Community Development, Division of Codes and Standards, memorandum of May 27, 1980.
6. T.C. Wang and J.L. Bricker, "2-Butanone and Tetrahydrofuran Contamination in the Water Supply," Bull. Environm. Contam. Toxicol., 23, 620 (1979).
7. California Analytical Laboratories, Inc., report #11501 to Raymond Leonardini of May 15, 1980.
8. California Analytical Laboratories, Inc., report #11614 to Raymond Leonardini of June 10, 1980.
9. Marc Lappe' letter to Mr. Myron Moskovitz and accompanying SNARL on trichloroethylene and toxicity data for other chemicals of February 14, 1980.

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APPENDIX

Not all of the documents referred to in the text are reproduced here. Total pages for these documents number over 100.

Interested parties may contact either the California Department of Health Services or the California Pipe Trades Council for a copy of:

1. The Montgomery Report;
2. Plumbing plan for 2-bath house;
3. California Department of Housing and Community Development memo;
4. Wang Study;
5. EPA SNARL on trichloroethylene.

The other documents are reproduced in the following pages.

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DEPARTMENT OF HEALTH SERVICES/DEPARTMENT OF INDUSTRIAL RELATIONS

HAZARD ALERT SYSTEM (HALTS)

2151 BERKELEY WAY

BERKELEY, CA 94704



May 22, 1980

Mr. Ray Leonardini
717 K Street
Suite 510
Sacramento, CA 95814

Dear Ray:

You asked me to provide you and other labor representatives with the methodology we plan to use in evaluating the safety of any observed solvents, PVC, monomer, plasticizer or other organic chemicals or metal ions in water carried by plastic or metal pipes.

For non-mutagens and non-carcinogens (refer to letter to Myron Moskovitz of February 13 sent under separate cover) we will determine water-borne permissible exposures based on equivalent doses permitted in workplace settings. This means that if a worker is permitted to be exposed to 200 ppm of methyl ethyl ketone (MEK) daily for a 40 hour work week, we will calculate the amount of MEK he or she would likely absorb in the course of those five days of work, incorporating an appropriate lung retention and body weight factor.

Having obtained this absorption value (expressed as mg/kg) we will then compute an equivalent amount for the most vulnerable member(s) of the population, specifically newborns and children, by extrapolating from the adult value to a child value using a body weight conversion--a standard pharmacology procedure. We will then calculate a permissible dose by using a safety factor of 100 and assuming that one liter of water is ingested per day for a child, and two liters for an adult. This process is shown schematically in the accompanying table.

If an agent is found in the leaching study water that has other than acute toxic effects, i.e., teratogenic, carcinogenic and/or mutagenic effects, a more rigorous risk estimation process will be needed. In general we will follow the procedures used by EPA in preparing SNARL documents, a copy of which is enclosed for TCE.

We are presenting this information to you in written form to corroborate our orally expressed position at earlier meetings. However, we wish to emphasize that these methodologies provide only broad guidelines for our evaluation. Should, for example, a solvent or a metal be shown to have chronic neurotoxicity, we would want a more stringent safety factor than the "100" one we have proposed. You will also note the similarity in our approach to that used in the January 20, 1980, letter to Mr. Turner from Beverlee Myers.

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Any comments you or your toxicological consultants might wish to make would be welcome; however, any responsibility for the most suitable evaluation process rests with HALTS and its staff. You will be notified as a further courtesy should we introduce any modifications of the general approach outlined here. Your comments or questions regarding either our rationale or the actual methodologies to be used are welcome.

Sincerely,



Marc Lappe', Ph.D.
Chief, Hazard Alert System

Enclosure

ml:vk

BFG06932

20810029

Table I

1. Current or Recommended TLV (TWA)
(mg/m³)

multiplied by

2. Volume of Air Inhaled by worker
per work day (mg/day)

multiplied by

3. Work Week (assume 40 hours)
or 5 days

multiplied by

4. Retention Factor

equals

5. Amount of Substance Absorbed
by worker per week (mg)

divided by

6. Weight of worker
(assume 70 kg)

equals

7. Dose on body weight basis
(mg/kg)

divided by

8. Seven day week

equals

9. Daily dose on body weight basis
(mg/kg)

multiplied by

10. Child or newborn body weight

divide by

11. Safety factor (100)

equals

12. Maximum allowable dose child
or newborn (mg)

divide by

13. Volume of water consumed per day
(assume one liter)

equals

14. Maximum allowable concentration
in water (mg/l)

an appropriate
± confidence
interval

BFG06933

20810030

Memorandum

445-1248

67-47-A

To : Donald Turner, Director
Housing and Community Development
921 Tenth Street
Sacramento, CA 95814

Date :

Subject: Consideration of Health
Hazards Associated with Use
of PVC Pipe Cements

from : Office of the Director

As requested, the Department of Health Services has reviewed information related to possible health hazards associated with polyvinyl chloride (PVC) pipe. The Department must adopt the position that it cannot support the use of PVC pipe until it is shown that residues of solvents used to join PVC pipes do not enter drinking water in amounts significant to health.

The Department has reviewed literature related to the effects on water quality from PVC pipe. The Environmental Protection Agency reports indicate that there is little release of the carcinogenic vinyl chloride monomer from the pipe into drinking water.^{1,2} Under appropriate controlled conditions of manufacture, the pipe itself appears to be safe for carrying drinking water.

Of greater concern to the Department are the primers and solvent cements used to join PVC pipe. These include tetrahydrofuran (THF), dimethylformamide (DMF), cyclohexanone, and methyl-ethyl-ketone (MEK). MEK is neurotoxic, particularly in the presence of certain other ketones, and DMF is hepatotoxic, an effect potentiated by ethanol.

Recently, the Threshold Limit Values (TLV's) have been reduced for both cyclohexanone (from 50 ppm to 25 ppm) and for DMF (to 10 ppm). Both MEK and THF have been shown to leach into water that is left standing in the pipes,³ and it is reasonable to assume, until proven otherwise, that the other two solvents, DMF and cyclohexanone, do also.

There are, at present, no water quality criteria standards known to the Department which set acceptable levels for these chemicals in drinking water. The Department has decided as an a priori margin of safety, that the dose absorbed in drinking water per week by the population should be less than one one-hundredth (10^{-2}) of the TLV/TWA, the level that OSHA allows the industrial worker to breathe at the worksite per week.

Draft, received by
Public and Environmental
Health Division

JAN 28 1960

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This should be considered the smallest acceptable margin of safety because exposures to these chemicals in drinking water affects:

1. the general population; and consequently a much larger number of people than just the worker population with industrial or installation exposure; and
2. high risk groups in the population; e.g., pregnant women and infants.

Calculations presented in the Appendix may demonstrate that these chemicals may enter drinking water in amounts that could be of health significance. According to these calculations, a developing child could be exposed to DMF at levels 1/3 the TLV/TWA industrial exposure (on a per kilogram basis) and to cyclohexanone at 1/10 the TLV/TWA industrial exposure. Even with the compounds MEK and THF the exposure would be 1/60th the TLV/TWA — certainly not a broad margin of safety. Exposure of adults to DMF and cyclohexanone would also lack an adequate safety margin.

The brain of the fetus or developing infant is more susceptible to neurotoxic agents than is that of the adult. Given these calculations and discussion, the Department of Health Services must adopt the position that it cannot support the use of PVC pipe until it is shown that residues of these solvents do not enter drinking water in amounts significant to health.

If further discussion of this subject is desired, you may contact Dr. Donald Lyman, Deputy Director, Public and Environmental Health Division, Department of Health Services, (916) 445-1102.

Beverlee A. Myers
Director

Attachment

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APPENDIX

A study recently reported in the Bulletin of Environmental Contamination and Toxicology³ reports that water from PVC pipes installed 6 months earlier gave the following levels of MEK and THF as affected by the time the water resided in the pipes before use:

<u>Residing Time</u> <u>(hours)</u>	<u>MEK</u> <u>(ppm)</u>	<u>THF</u> <u>(ppm)</u>
0	0	0
4	0.4	1.0
8	0.6	1.7
16	1.8	5.8
24	2.2	8.9
48	3.9	12.0
64	4.5	13.0
96	4.5	13.0

Since no water quality criteria are available for these chemicals, limits for these substances are estimated from quantities respired by a worker breathing in an atmosphere at the TLV for a work week:

Quantities of DMF, THF, MEK, and cyclohexanone absorbed by a 70 kg worker breathing each substance at the TLV 8 hours per day:

A. DMF: TLV for DMF is 10 ppm (30 mg/M³)

Breathing 10 M³ per 8 hour day, he will be exposed to and potentially absorb:

300 mg DMF or 4.3 mg/kg/day or 21.4 mg/kg/work week

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B. THF or MEK: TLV for THF and MEK is 200 ppm (590 mg/M³)

Breathing 10 M³ per 8 hour work day, he will be exposed to and potentially absorb:

5900 mg THF or MEK/day or 84.3 mg/kg/day or 421 mg/kg/work week

C. Cyclohexanone: TLV for cyclohexanone will be 25 ppm (100 mg/M³)

By the same reasoning:

1000 mg cyclohexanone/day or 14.3 mg/kg/day or 71.4 mg/kg/work week

Now to estimate water exposure:

	<u>If drinking water contains 1 ppm of substance</u>	<u>If drinking water contains 10 ppm of substance</u>
For 70 kg person drinking 2 liters/day	2 mg/day intake or 0.03 mg/kg/day or 0.2 mg/kg/7-day week	20 mg/day intake or 0.29 mg/kg/day or 2 mg/kg/7-day week
For 10 kg child drinking 1 liter/day	1 mg/day intake or 0.1 mg/kg/day or 0.7 mg/kg/week	10 mg/day intake or 1 mg/kg/day or 7 mg/kg/week

It is apparent that water ranging from 1 ppm to 10 ppm of DMF would expose an infant (on a per kilogram basis) from 1/3 to 1/30 the limit of DMF an adult may be exposed to in a week at work. By the same reasoning the infant would be exposed to from 1/10 to 1/100 the cyclohexanone limit and from 1/60 to 1/600 the THF and MEK limit. These exposures are unacceptably high and do not afford the 10⁻² margin of safety the Department considers necessary.

References:

1. Preliminary Assessment of Suspected Carcinogens in Drinking Water, U.S.E.P.A., December 1975.
2. Dressman, R.C., McFarren, E.F.: Determination of Vinyl Chloride Migration from Polyvinyl Pipe Into Water; J. Amer. Water Works Assoc. 70:1:29-30, 1978.
3. Wang, T.C., Bricker, J.L.: 2 Butanone (methyl-ethyl-ketone) and tetrahydrofuran (THF) in the Water Supply; Bull. Environ. Contam. 23:620-623, 1979.

BFG06937

20810034

CHARLES J SODERQUIST, Ph.D
DIR. OF ENVIRONMENTAL CHEMISTRY

JERRY L. WILSON, PH.D.
SENIOR CHEMIST
SECRETARY

401 NORTH 16th STREET
SACRAMENTO, CALIFORNIA 95814
(916) 444-9602

June 10, 1980
Lab No. 11614
Submitted: 6/5/80

Nine water samples received in 40 mL septum-capped vials. Analysis for organic contaminants. The following samples were collected by Dr. C.J. Soderquist of California Analytical Labs on June 5, 1980.

1. 70-1-- Hospital, new basement, capped CPVC line; initial effluent
2. 70-2-- Hospital, new basement, capped CPVC line; after about 1 pint flow
3. 70-3-- Hospital, new basement, capped CPVC line; after about 3-5 gallons flow
4. 70-4-- Hospital, new basement, capped CPVC line; after installation of hose bib and 5 minutes full flow
5. 70-5-- Hospital, 1st floor, incoming water 6' before tie-in to CPVC system
6. 70-6-- Hospital, new basement; same as sample 4 after 30 minutes stagnation
7. 70-7-- Hospital drinking fountain in old basement
8. 70-8-- Hospital, new basement; same as sample 4 after 43 minutes stagnation
9. 70-9-- Hospital, new basement; same as sample 4 after 144 minutes stagnation

Selected samples were analyzed for methylethylketone (MEK), tetrahydrofuran (THF) and cyclohexanone by direct aqueous injection using flame-ionization gas-liquid chromatography and for halogenated volatile organics using purge/trap Coulson gas-liquid chromatography.

Charles J. Soderquist
Charles J. Soderquist, PhD
Dir. of Environmental Chemistry

BFG06938

CONCLUSIONS

PAUL A. TAYLOR, Ph.D.
PRESIDENT

CHARLES J. SODERQUIST, Ph.D.
DIR. OF ENVIRONMENTAL CHEMISTRY

ANTHONY S. WONG, Ph.D.
VICE PRESIDENT

JERRY L. WILSON, Ph.D.
SENIOR CHEMIST
SECRETARY

California Analytical Laboratories, Inc.

401 NORTH 16th STREET
SACRAMENTO, CALIFORNIA 95814
(916) 444-9802

June 10, 1980
Lab No. 11614
Submitted: 6/5/80

Ray Leonardini
717 "K" St. Suite 510
Sacramento, CA 95814

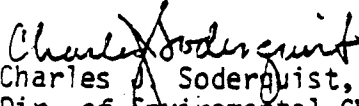
Nine water samples received in 40 mL septum-capped vials. Analysis for organic contaminants. The following samples were collected by Dr. C.J. Soderquist of California Analytical Labs on June 5, 1980.

Sample I.D.

1. 70-1-- Hospital, new basement, capped CPVC line; initial effluent
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8. 70-8-- Hospital, new basement; same as sample 4 after 43 minutes stagnation
9. 70-9-- Hospital, new basement; same as sample 4 after 144 minutes stagnation

Selected samples were analyzed for methylethylketone (MEK), tetrahydrofuran (THF) and cyclohexanone by direct aqueous injection using flame-ionization gas-liquid chromatography and for halogenated volatile organics using purge/trap Coulson gas-liquid chromatography.

Results are attached.


Charles J. Soderquist, PhD
Dir. of Environmental Chemistry

BFG06939

20810035

Ray Leonardini
 Lab No. 11614
 June 10, 1980
 page 2

TABLE I

Sample	mg/L (ppm) found		
	MEK	THF	cyclohexanone
11614-1		240	<5.0
carpet -2		260	<5.0
carpet -3	8.7	160	<5.0
-4	<1.0	<1.0	<5.0
-5	<1.0	<1.0	<5.0
-6	<1.0	<1.0	<5.0
-7	<1.0	<1.0	<5.0
-8	<1.0	<1.0	<5.0
-9	<1.0	<1.0	<5.0

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TABLE II
Compounds for which entries are made below were detected by the purge/trap technique with Coulson gas-chromatography. All others were absent at the stated detection limit.

NO BLANK WATER TEST
ppb found

COMPOUNDS	11614-1*	11614-3*	11614-5*	11614-9
Dichlorodifluoromethane				
Chloromethane				
Vinyl chloride	2.7	10		
Bromomethane				
Chloroethane				
Trichlorofluoromethane				
Dichloromethane				
1,1-Dichloroethylene				
1,1-Dichloroethane				
trans-1,2-Dichloroethylene				
Chloroform	14	8.7	60	54
1,1,2-Trichloro-2,2,1-trifluoroethane				
1,2-Dichloroethane				
1,1,1-Trichloroethane				
Carbon Tetrachloride	0.83	0.20		
Dibromomethane				
Bromodichloromethane	1.2	0.72	4.0	3.8
2,3-Dichloropropylene				
1,2-Dichloropropane				
Trichloroethylene	2.1	1.7		
cis-1,3-Dichloropropylene				
1,1,2-Trichloroethane				
Dibromochloromethane				
1,2-Dibromoethane				
Bromoform				
Tetrachloroethylene	1.5			
1,1,2,2-Tetrachloroethane				
Chlorobenzene				

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Detection limit:

0.5 ppb

0.5 ppb

0.5 ppb

0.5 ppt

NOTE: The bracketed pairs cannot be distinguished by this technique.

* Contains unidentified compounds at the low ppb level. 20810037

<u>CAL I.D.</u>	<u>Sample description</u>
11501-1	63-1a South side hose bib 1120 hrs.
-2	63-1b South side hose bib (duplicate) 1120 hrs.
-3	63-2 South side hose bib after approx. 3 minutes flow 1125 hrs.
-4	63-3 West side (south end) hose bib after approx. 0.5 minute flow 1130 hrs.
-5	63-4a North side hose bib after approx. 5 minutes flow 1135 hrs.
-6	63-4b North side hose bib after approx. 5 minutes flow (duplicate) 1135 hrs.
-7	63-5 South side hose bib after approx. 18 minutes flow (BROKEN)
-8	63-6 West side (south end) hose bib 1420 hrs.
-9	63-7 West side (south end) hose bib after approx. 0.5 minutes 1420:30 hrs.
-10	63-8 West side (south end) hose bib after approx. 1 minute 1421 hrs.
-11	63-9 West side (north end) hose bib 1427 hrs.
-12	63-10 West side (north end) hose bib after approx. 1 minute 1428 hrs.
-13	63-11 South side (by garage) hose bib 1431 hrs.
-14	63-12 South side (by garage) hose bib after approx. 1 minute 1432 hrs.

METHODS: Various analytical approaches were used to determine the nature and level of contaminants present in the water collected from the house.

A. FID-GLC determination of THF, DMF, MEK and cyclohexanone. Samples were analyzed by direct aqueous injection for THF (tetrahydrofuran), DMF (dimethylformamide), MEK (methyl ethyl ketone) and cyclohexanone by flame-ionization gas-liquid chromatography (10 foot, 20% SP-1000 column) against authentic samples of these compounds. DMF gave a poor response to the analysis; its presence or absence was not accurately determined. Results are given in Table I.

B. Coulson-GLC determination of volatile, halogenated organics. Samples were analyzed by the purge-trap technique using Coulson gas-liquid chromatography (10 foot, 0.2% Carbowax 1500 on Carbopak C Column). Results are given in Table II.

C. FID-GLC and ECD-GLC determination of phthalate esters. Samples were analyzed for phthalate esters (e.g., dimethyl-, diethyl-, dibutyl-, butylbenzyl-, diethylhexyl- and dioctyl phthalates) by extraction with toluene and with carbondisulfide. The toluene extracts were examined by electron capture gas-liquid chromatography (6 ft. 1.5% OV-17/1.95% QF1 column) and the carbondisulfide extracts by flame-ionization gas-liquid chromatography (3% SP-2250 column). Results of the FID analysis are given in Table III.

D. GC/MS confirmation. Certain samples were examined by gas-chromatography mass-spectrometry to confirm the presence of suspected contaminants. Both the purge/trap (for volatiles) and extract injection (for phthalates) techniques were used.

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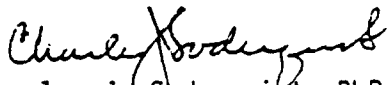
2081003C

DISCUSSION: GC-MS analysis of sample 11501-4 confirmed that THF, MEK and cyclohexanone were present. GC-MS analysis of the toluene extract of sample 11501-1 confirmed the presence of diethylhexylphthalate.

Samples collected from the south side hose bib, which is the furthest sampling point from the incoming (north side) source, contained high levels of MEK, THF and cyclohexanone and low levels of carbontetrachloride, trichloroethylene and tetrachloroethylene. Samples collected from the incoming (north side) source contained no detectable amounts of these contaminants; only those volatiles which are common to chlorinated water were present (Table II).

Data of three sets of samples can be interpreted in terms of time-of-flow. In two cases, an increase in contaminant levels is apparent after some flushing: Sample 11501-2, collected just after 11501-1, and sample 11501-12 collected about one minute after 11501-11. A decrease in contaminant levels following prolonged flow is apparent from comparison of sample 11501-3 (3 minutes flow) to 11501-1 and -2 and from samples 11501-9 and -10 to sample 11501-8. It is obvious from these comparisons that the potential hazard to a consumer will be dependent upon the pattern of water use in the home.

Analysis for phthalate esters indicated that diethylhexylphthalate was present in the two samples examined (Table III). It would appear from this limited data that diethylhexylphthalate was present at an elevated level in the south side sample. However, the sample vials and sampling protocol used in this study were intended for volatile organics and do not represent the best protocol available for semivolatile organics--especially for the ubiquitous phthalates. Further work would be necessary to confirm the validity of this preliminary assessment.


Charles J. Soderquist, PhD
Dir. of Environmental Chemistry

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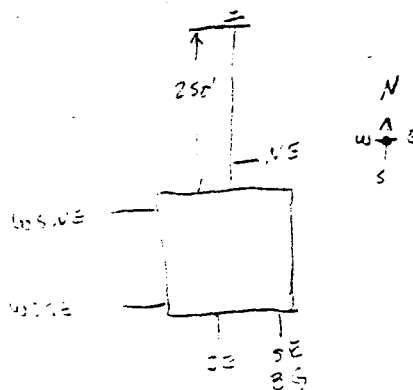
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TABLE I

CAL I.D.	mg/L (ppm) found			
	MEK	THF	cyclohexanone	DMF
11501-1	5.5	(47) 5.5. 1120	2.7	<5.0
-2	(8.0)	(92) SS 1120 1420 1431	ND	ND
-3	<0.5	1.0 SS 1120 1420 1431	ND	ND
-4	3.1	(24) WSSE 1420 1431	1.4	<5.0
-5	<0.5	<0.5 NIS 5 m flow 1135	ND	ND
-6	<0.5	<0.5 NIS 5 m flow 1135 dup at 5	ND	ND
-7	Broken			
-8	4.1	37 WSSE 1420	0.8	<5.0
-9	<0.5	<0.5 WSSE 1420 1431	ND	ND
-10	<0.5	<0.5 WSSE 1421	ND	ND
-11	0.5	5.0 WSSE 1427	ND	ND
-12	1.3	(10) WSSE 1428	ND	ND
-13	3.6	(27) SSBS 1431	ND	ND
-14	<0.5	0.6 SSBS 1432	ND	ND

ND = Not Determined



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TABLE II

Compounds for which entries are made below were detected by the purge/trap technique with Coulson gas-chromatography. All others were absent at the stated detection limit.

COMPOUNDS	11501-2	11501-5		
Dichlorodifluoromethane				
Chloromethane				
Vinyl chloride				
Bromomethane				
Chloroethane				
Trichlorofluoromethane				
Dichloromethane				
1,1-Dichloroethylene				
1,1-Dichloroethane				
trans-1,2-Dichloroethylene				
Chloroform	140 ppb	74 ppb		
1,1,2-Trichloro-2,2,1-trifluoroethane				
1,2-Dichloroethane				
1,1,1-Trichloroethane				
Carbon Tetrachloride	14 ppb			
Dibromomethane				
Bromodichloromethane	16 ppb	20 ppb		
2,3-Dichloropropylene	2.5 ppb			
1,2-Dichloropropane				
Trichloroethylene				
cis-1,3-Dichloropropylene				
1,1,2-Trichloroethane	3.5 ppb	3.6 ppb		
Dibromochloromethane				
1,2-Dibromoethane				
Bromoform				
Tetrachloroethylene	6.0 ppb			
1,1,2,2-Tetrachloroethane				
Chlorobenzene				

Detection limit: 0.5 ppb

NOTE: The bracketed pairs cannot be distinguished by this technique.

BFG06945

TABLE III

<u>Sample</u>	<u>diethylhexylphthalate</u>
11501-1/-2 composite	0.11 mg/L (ppm)
11501-5/-6 composite	0.02 mg/L (ppm)

BFG06946



9

February 14, 1980

Mr. Myron Moskovitz
Chairman
Commission on Housing & Community
Development
921 10th Street
Sacramento, CA 95814

Dear Mr. Moskovitz:

I wanted to provide you and the Housing and Development Committee a interim progress report on the work of the HALTS unit on the issue of potential health hazards for plastic pipe.

To date, the HALTS staff have completed an initial review of the complete toxicology literature on each of the major solvents; initiated field measurements on worker exposures to solvent cements or primers while installing pipe; and commenced planning with industry to do a full-scale test of PVC pipe to determine how much solvent, if any leaches from pipe under a full range of operating conditions.

1. Toxicology

The attached Appendix summarizes briefly the major toxicological features of the solvents. I wish to emphasize that such data provides only a baseline against which to measure worker exposures and leached solvent. By themselves, such toxicity information provide little or no guidance for policy determinations. Only actual measurements of exposure data will suffice for our review. Our final evaluation will thus be based on data measured in the workplace or in the pipe itself. These tests will be conducted under conditions set by the Department with the cooperation of industry representatives as outlined below (see 3). Every effort will be made to ensure that the test conditions meet the concerns of all factions involved, consistent with good study design and objective scientific analysis.

2. Worker Hazard Evaluations

Field measurements are going forward at a number of sites given to us by workers or their representatives with the objective of deriving "worst-case" scenarios for exposure. Preliminary data based on MEK exposure in a closed site suggests that even under such extreme conditions workers may not be exposed to levels that pose major health risks. I would emphasize the very preliminary nature of such a finding, and again stress that our final report (due May 1, 1980) will embrace as full a range of worker exposure as is practicable.

3. Field Test of Leaching

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In order to resolve the contradictory and largely anecdotal reports of the safety of potable water transported through plastic pipe, HALTS has reached agreement with Mr. J. J. Blumenkrantz of the R. & G. Sloane Mfg. Company of Sun Valley, California, to conduct a full series of tests of water carried by plastic pipe under supervision of the Department's staff and the most rigorous test conditions possible. Again, "worst possible" test conditions will be assessed with maximum numbers of fittings per unit length of pipe; "sloppy" solvent technique; "aggressive" (ie high solvency) water; and maximum temperatures used as well as appropriate "normal" condition and, hopefully, iron pipe controls.

4. Comments

Our findings to date, based on extensive contacts with industry (including Monsanto and Dupont representatives) lead us to believe that the issue of worker safety and solvent leaching has been inadequately studied. To cite but one specific case, a call to Dr. Robert Olson of St. Louis University School of Medicine revealed that his conclusions on worker safety (communicated in a telegram dated 1/29/80) were based on theoretical calculations rather than field measurements. Similarly, calls to industry references on solvent safety vis a vis leaching (Continental Water Co., Indianapolis, Indiana and El Paso, Texas) yielded no contacts who had actually measured solvent amounts in water.

In view of the dearth of usable data on actual exposures and our previous concerns about potential health effects, we believe that the original study we outlined in our letter of December 13, 1979, should now be conducted. We have begun the necessary tests and study designs and fully expect to have definitive results and evaluations available for your committee by May 1, 1980.

I hope the Committee considers this prospect in its deliberations February 26. The resolution of probable health effects prior to the expanded use of plastic pipe would seem to us to be in everyone's best interest.

Sincerely,



Marc Lappe', Ph.D.
Director, HALTS

Enclosure

cc: Donald Lyman
Beverlee Myers
Louis Pappan

ml:vk

BFG06948

00000000

General Summary

Toxicity of PVC-Pipe Cement Solvents Exclusive of Carcinogenicity

I. Specific Solvents

A. Methyl Ethyl Ketone (MEK, butanone)

1. Central Nervous System Depression

MEK belongs to the class of hydrocarbon solvents that have central nervous system (CNS) depressant (i.e. anaesthetic or narcotic) effects. The precise potency of MEK in this regard is unknown, but it is generally considered weak. Estimates of the minimum exposure level that might produce narcotic effects range from 300 to 600 ppm. Since MEK produces mucosal irritation beginning for some persons at 100 ppm, and the 200 ppm threshold value was established to protect against irritation, it is generally believed that this provides a buffer against CNS effects. However, neurobehavioral effects such as decreased reaction times occur before or at lower levels than obvious CNS depression. It is possible that prolonged exposure to near-threshold levels (100 - 200 ppm) of MEK would result in measurable deficits in performance, but this has not been studied.

2. Neurotoxicity

A number of solvents related to MEK have been shown to cause nerve damage in men and usually also in experimental animals. Most prominent are n-hexane and methyl n-butyl ketone (MBK) both of which are metabolized to a six carbon molecule, 2,5-hexanedione, the active neurotoxin. Other probable neurotoxins formed from the metabolism of ketones are also six-carbon molecules. MEK is a four-carbon molecule that is metabolized to 2-butanol, 3-hydroxy-2-butanone and 2,3-butanediol.¹ Other possible metabolites include acetaldehyde, acetone, methanol and ethanol.² There is no reason to suspect any of these four carbon or shorter molecules would result in nerve damage (peripheral neuropathy) as a result of occupational exposure to MEK.

In support of this position, animal data suggests that MEK alone does not produce peripheral neuropathy. Rats exposed continuously to MEK at 1,125 ppm for five months showed no evidence of neurotoxicity.³ (However, this study showed that MEK potentiated the neurotoxic effect of MBK in rats, a finding that was not confirmed in cats.)⁴

There is little evidence that MEK alone can produce peripheral neuropathy in humans. Allan et al⁵ reported that workers in a plant exposed to MEK alone showed no evidence of neuropathy, while those exposed to MBK did.

However, it is relevant of solvent mixtures that one worker developed a neuropathy after exposure to MEK and THF, neither of which is known to be neurotoxic.⁶ Three workers in a shoe factory with cutaneous exposure to MEK and toluene (also not known to be neurotoxic) developed peripheral neuropathies.

20810046

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Case reports have suggested that MEK might potentiate the neurotoxic effects of MBK, n-hexane⁸ and methyl 1-butyl ketone,⁹ although such potentiation is impossible to prove in such cases.

In summary, there is no convincing evidence that MEK alone produces nerve damage, a conclusion generally supposed by data from an estimated 3,000,000 workers who are exposed to MEK in the U.S. There may be potentiation of other neurotoxins. Although none of the other components under consideration here are known neurotoxins, because of one previous case report with THF and because such effects may be evidenced only after long-term exposure, this possibility must be considered whenever MEK is used in combination with other solvents.

A specific recommendation in this regard will be made after a full review of the composition of solvents in use and actual field measurement of combined exposures is made.

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B. Tetrahydrofuran

1. CNS Depression

This has been seen apparently only with high-level exposure to animals e.g. 10-25,000 ppm. It is unclear as to what the basis for the TLV of 200 ppm is. THF is the most volatile of the four solvents.

2. Neurotoxicity

Refer to above for case report of nerve damage with use of a mixture of 60% THF adhesive with MEK solvent (MEK ref. 9). A pipefitter working with THF, cyclohexanone and acetone developed parosmia (unpleasant sensation of smell) and hyposmia (decreased sensitivity of smell), although exposure levels were not reported.¹ It is uncertain as to whether this might be a common but under reported condition or an isolated case.

C. Cyclohexanone

1. CNS Depression

Evidence of CNS depression was seen in rabbits exposed to 190 ppm for prolonged periods. Cyclohexanone is a mucosal irritant at 75 ppm, and so the TLV is 25 ppm. Given this and very low volatility, there is low risk for this toxicity with most usage.

2. Other

There is no evidence that cyclohexanone is neurotoxic, but few animal studies examined the peripheral nervous system. The rabbits exposed to 190 ppm in the 1943 study showed some animals with liver and kidney damage. There are no reports of such in humans. Refer to above (THF ref. 1) for case of disturbed olfactory function with exposure to cyclohexanone and THF.

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D. Dimethyl formamide (DMF)

1. Gastrointestinal

Exposure to repeated inhalation of DMF results in damage to multiple organs in experimental animals, particularly liver and pancreas.^{1,2} Repeated exposure to 100 ppm resulted in some animals with mild liver necrosis. Thus the TLV is set at 10 ppm. Liver injury and abdominal pain possibly caused by pancreatitis has been reported in case reports of workers.³ Where the level of exposure was reported it appeared to be excessive. However, OSHA is currently investigating a plant situation where a series of cases of liver damage have been associated with the use of DMF. This investigation is just beginning. Conclusions regarding the potential hepatotoxicity of DMF in the workplace should be held pending the outcome of this study.

2. Alcohol Interaction

Alcohol is metabolized to acetaldehyde, a potent vasodilator and quite toxic, which is then metabolized by acetaldehyde dehydrogenase to a less toxic substance, acetate. Disulfiram (antabuse²) is used to treat alcoholics as it inhibits the metabolism of acetaldehyde, resulting in a reaction of cutaneous flushing, headache, nausea, vomiting and hypotension. When severe, it has been fatal, but is usually simply extremely unpleasant. DMF, through its metabolite n-methylformamide, also inhibits acetaldehyde dehydrogenase, and has resulted in this reaction with alcohol in human and animals. The amount of DMF necessary to produce this reaction is unknown. In animals exposure to 1,000 ppm DMF for three days at 4 hr/day significantly increased acetaldehyde levels after alcohol administration in rats.⁵ However, a "no effect" exposure level was not determined. Nineteen of 102 workers exposed to up to 200 ppm of DMF noted reactions upon drinking alcohol.⁶ One worker had a reaction following exposure to 30 ppm for four hours, plus possible cutaneous exposure.⁷ Although there are no reports of this reaction with exposure below the TLV of 10 ppm, in order to determine its frequency all workers exposed to any level should be warned of this, and all possible reactions reported.

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