DRAFT #2
MAY 2, 1980

[May 9, 1980]

Docket Officer
Docket H-034
Room S6212
U.S. Department of Labor
200 Constitution Avenue, N. W.
Washington, D. C. 20210

Re: Docket H-034, Occupational Safety and Health Administration Request for Information on Vinyl Chloride and Polyvinyl Chloride - 44 Fed. Reg. 74928, December 18, 1979; 45 Fed. Reg. 668, January 29, 1980

Dear Sir:

Pursuant to Section 4 of the Administrative Procedure Act, as amended, 5 U.S.C. Section 553(c), and the above-referenced U.S. Department of Labor - Occupational Safety and Health Administration (OSHA) Request for Information on Vinyl Chloride and Polyvinyl Chloride and the subsequent Notice extending the time during which interested persons are invited to submit written data, views, and comments with regard to the issues described in the original Notice, The Society of the Plastics Industry, Inc. (hereinafter referred to as "SPI" and/or "The Society"), by its attorneys, hereby submits in quadruplicate certain information which is intended to be responsive to the Agency's Request.

DRAFT

I.

NTRODUCTION AND SUMMARY OF INFORMATION PRESENTED

SPI is a corporation organized under the Not-for-Corporation law of the State of New York. Its 1500 companies and individuals and 67 operating units in-hose who supply raw materials; process or manufacture :s or plastics products; engineer or construct molds ilar accessory equipment for the plastics industry; gage in the manufacture of machinery used to make plas-roducts and materials of all types. SPI is the major al trade association of the plastics industry. The ty of its members are the processors and converters : plastics resins and end products which represent 75% dollar volume of sales of plastics in this country; membership also represents 95% of all plastics materials achinery manufactured in the U.S.A.

The Society's concern with vinyl chloride and poly-chloride begins with the manufacture of the ethylene oride (used to manufacture the monomer) and the manufacture nyl chloride monomer (VCM), carries forth through its merization into polyvinyl chloride (PVC), continues with various processes which convert the PVC resin into its itude of end uses, and includes, ultimately, the recycling isposal of PVC products. In the United States there

chloride plants, 13 plants which produce
omer and 42 polymerization plants. Twenty-
esenting over 95% of the domestic VCM and
ıctive members of SPI's PVC Safety Group.

Safety Group has prepared the information,
ntained in what follows and it is presented
orresponds in large part to the explicit re-
ation contained in the Agency's Notice.
y, The Society's responses to the questions
.ows:
ı is aware of the studies on vinyl
oride sponsored by Imperial Chemicals
ustries, Limited; Solvay et Cie; Mon-
ison; and Rhone-Poulenc Industries
Dr. Maltoni's laboratory in Bologna,
ıly.
ese most recent data of Maltoni indi-
te possible effects in rats exposed
10 ppm of vinyl chloride but no increase
tumors was found in experimental rats

exposed below 10 ppm. It is worthy to note that in these studies Dr. Maltoni observed no evidence of lung or brain tumors. It is clearly evident that rodents are more susceptible than humans and that human experience should be given higher importance than animal studies because the animal data have predicted a cancer incidence rate 500 times higher than has been observed in man.

2. It has been reported in the literature that VCM can exert a carcinogenic effect transplacentally; however, the phenomenon has only been demonstrated in pregnant ~~female~~ rats exposed to very high concentrations. ~~This study~~ Additional work needs to be ~~repeated~~ done using lower, more realistic doses since available data indicated that the 2 routes rates of metabolism in the rat shift as exposure concentrations of vinyl chloride change. Vinyl chloride did not cause significant embryonal or fetal toxicity and was not teratogenic in studies in

rats, mice or rabbits. We know of no valid scientific paper associating vinyl chloride with human birth defects. ~~nor in animals at levels of exposure below those causing frank maternal toxicity.~~

NB Now →

3. Experimental studies show no carcinogenic or other toxic manifestations related to polyvinyl chloride exposure. Solid PVC is inert and the effects resulting from experimental exposure to PVC dust appear to be characteristic of nuisance dusts in general, that is, they are limited to deposition of dust and have no adverse functional effects.

4. Although there is no new epidemiologic data on vinyl chloride exposure, The Society has contracted for a complete analysis of all the relevant epidemiologic data, particularly since many of the studies which have been reported represent investigations of the same population of subsets thereof. Considering the magnitude of this project, it will not be finished

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by the May 9, 1980 deadline associated with the Request but these materials will be submitted to the Agency when they have been completed.

5. The Society is not aware of any new case reports on cancer associated with vinyl chloride or polyvinyl chloride but is submitting to the Agency the most recent compilation of all liver angiosarcoma deaths due to VCM.

6. It has been demonstated that if mutagenic effects occur as ~~measured~~ MONITORED (CHROMOSOMAL ANALYSIS OF by circulating lympocytes, they were the results of high exposures; the ~~measured effects~~ CHANGES have not been permanent changes since they were reversible. The ~~effects~~ CHANGES did not occur at lower levels of exposure. The clinical significance of ~~THE CHANGES~~ REVERSIBLE CHANGES is not known.

7. Being a poorly soluble gas, vinyl chloride does not accumulate from chronic exposure but, rather, is rapidly exhaled after exposure ceases. Hence, there can be no body burden in the usual ~~manner~~ SENSE IN which the term is applied.

8 and 9. An overview of PVC manufacturing operations, types of resin, residual monomer levels, and PVC dust experience is presented with information on monitoring results, control technology and personal protective devices.

10. SPI is unaware of any change in the types of occupations, jobs and industries which present a potential for exposure to VCM or PVC. The Society has no data on the numbers or sexual breakdown of employees exposed.

11. The VCM/PVC industry is presently engaging in the use of appropriate engineering controls, work practices and personal protective equipment, is trying to stay in compliance with the existing standard, and knows of no additional, feasible measures to reduce exposure below the present level. PVC dust is adequately regulated by OSHA's general dust control standards and has not been shown to be hazardous at lower levels.

The Society has also presented information in other areas in which the Agency has shown an interest and with regard to which industry has some information.

II.

SPECIFIC INDUSTRY RESPONSES TO INFORMATION REQUESTED

(1) Experimental Test Results for Carcinogenicity of Vinyl Chloride At Atmospheric Exposures Less Than 50 ppm

OSHA is aware of the studies on vinyl chloride sponsored by Imperial Chemicals Industries, Limited; Solvay et Cie; Montedison; and Rhone-Poulenc Industries in Dr. Maltoni's laboratory in Bologna, Italy.

These most recent data of Maltoni indicate probable effects in rats exposed to 10 ppm of vinyl chloride but no increase in tumors was found in experimental rats exposed below 10 ppm. It is worthy of note that in these studies Dr. Maltoni observed no evidence of lung or brain tumors. It is clearly evident that rodents are more susceptible than humans and that human experience should be given higher importance than animal studies.

These data were reported in detail at a recent OSHA/NIOSH/NIEHS supported Symposium, March 20 and 21 in Bethesda, Maryland. An unedited stenographic transcript and photographic copies of the slides are attached as Appendix A. In these studies, rats, mice and/or hamsters have been exposed to concentrations ranging from 30,000 ppm to 1 ppm. The attached summary statement by the European sponsors quotes Dr. Maltoni and indicates that extensive statistical evaluations of Dr. Maltoni's data have been completed. Appendix B. Dr. Maltoni summarized his animal studies as follows:

> ...the following tumours should be given proper attention viz, extrahepatic angiosarcomas, hepatomas, Zymbal gland carcinomas, liver angiosarcomas, neuroblastomas, nephroblastomas, forestomach papillomas and mammary carcinomas.
>
> In oncological terms, the meaning of the results at the lowest doses may be better evaluated by considering, not separately, but together, the tumours found to be VCM dependent. Thus the following results should be considered:
>
> at 25 ppm - In 120 animals, 5 liver angiosarcomas 4 Zymbal gland carcinomas and 1 nephroblastomas.
>
> at 10 ppm - In 120 animals, 1 liver angiosarcoma, 2 extrahepatic angiosarcomas and 2 Zymbal gland carcinomas.
>
> at 1mg/kg - In 150 animals, 3 liver angiosarcomas, 1 extrahepatic angiosarcoma, 1 hepatoma and 5 Zymbal gland carcinomas....

These data add to data previously published by Dr. Maltoni since tumors occurred in rats exposed to 25 or 10 ppm of vinyl chloride gas. The European Sponsors state,

> ...In addition, it is worthwhile emphasizing that none of the previously cited tumours have been observed at 5 ppm by inhalation and 0.03 mg/kg by ingestion....

These data will be published as part of the proceedings of Club de Cancerogenese Chemique held at the Curie Foundation in Paris, France, November 10, 1979. These proceedings which will be supplied to OSHA as soon as available, will contain an even more complete report of Maltoni's studies than was presented in Bethesda, March 20, 1980.

In regard to the response of laboratory animals to vinyl chloride gas, the attached paper by Gehring, Watanabe and Park is extremely pertinent. Appendix C. This paper indicates the necessity of considering the rate of metabolism and body size of different species when comparing the response of different species to vinyl chloride. Appendix D is a revision of this paper to include the latest and final data from Maltoni as cited in the transcript of the Bethesda meeting. These recalculations support even more strongly than previously, the need to consider these factors in interpreting animal data.

Differences such as those considered by Gehring, Watanabe and Park, no doubt are involved in the wide difference between the high incidence of angiosarcoma in small rodents and the much lower incidence in man.

It is clearly evident that rodents are more susceptible than humans and that human experience should be given higher importance than animal studies.

As observed by Dr. David Rall, Director of NIEHS, a wide difference exists between man and rodents. Appendicies E and F. He stated that in regard to angiosarcoma the available data

> ...predicted a cancer incidence rate 500 times higher than has so far been reported in man by epidemiological studies for vinyl chloride.... Appendix E.

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(2) Studies of Transplacental Carcinogenic and Teratogenic Effects in Humans or Animals at Any Level of Exposure to Vinyl Chloride

It has been reported that VCM can exert a carcinogenic effect transplacentally[1/2/]; however, the phenomenon has only been demonstrated in pregnant female rats exposed to high (10,000 or 6,000 ppm) concentrations of the material. ~~This study~~ ADDITIONAL WORK DONE needs to be ~~repeated~~ using lower, realistic doses since available data indicate that rates of metabolism in rats shift as exposure concentrations of vinyl chloride change.[3/] Vinyl chloride did not cause significant embryonal or fetal toxicity and was not teratogenic in studies in rats, mice or rabbits.[4/] We know of no valid scientific paper associating vinyl chloride with human birth defects, ~~nor in animals at levels of exposure below those causing frank materal toxicity~~.

EVEN AT LEVELS WHICH RESULTED IN MATERNAL TOXICITY

1. TRANSPLACENTAL CARCINOGENESIS

Maltoni has reported that exposure of female rats to 10,000 and 6,000 ppm of vinyl chloride has resulted in transplacental effects in their offspring. No data have

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1/ Maltoni, C., Vinyl Chloride Carcinogenecity: An Experimental Model for Carcinogenesis Studies. In "Origins of Human Cancer. Book A: Incidence of Cancer in Humans." H.H. Hiatt, J.D. Watson and J.A. Winsten, Cold Spring Harbor, Cold Spring University, 1977.

2/ Maltoni, C., Carcinogenicity Bioassays of Vinyl Chloride Monomer: A Model of Risk Assessment on Experimental Basis. Symposium Paper No. 1 (1980).

3/ ~~Ungvary paper~~. GEHRING - WATANABE, ETC ?

4/ John article from fn 7. - FULL CITATION

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been found in which pregnant animals have been exposed to lower concentrations. Rice[5/], although not having actually studied vinyl chloride in his laboratory, reviewed the subject of transplacental carcinogenesis. In discussing the above-mentioned work of Maltoni, Rice refers to the important role of biotransformation of VC to the probable carcinogenic metabolite. This metabolic transformation in the pregnant female, the possibility of a similar transformation in the fetus, the kinetics of placental transfer (which processes can be bidirectional) and the metabolic degradation in both the gravid female and the fetus all illustrate the complexity of transplacental carcinogenesis.

Rice also rightly points out that the probable carcinogenic metabolite in the case of VCM has a relatively short half-life. This would limit the times for transfer across the placenta to the fetus and distribution in the fetus. Although the data of Maltoni indicate that the probable carcinogenic metabolite either crosses the placental barrier or is formed in the fetus in sufficient concentration to elicit a carcinogenic response, the short half-life suggests that the effect would be minimized at lower levels of maternal exposure. Unfortunately, sufficient data are lacking on much of the foregoing, and therefore definitive conclusions cannot be reached.

5/ Rice, J., Transplacental Carcinogenic Effects. Symposium Paper No. 27 (1980).

Another complicating factor, even over and above those usually recognized, in extrapolating from Maltoni's transplacental carcinogenesis data in rats to a possible human situation is the knowledge that rats are far more sensitive to VCM than humans. In addition, there is a difference in placental structure between humans and rodents.

The following discussion of the possible effects of these differences in placentation with regard to teratogenesis is equally germane to the consideration of transplacental carcinogenesis:

> ...Both man and the test animals commonly used possess chorioallantoic placentae, but that of man is the hemochorial one consisting essentially of fetal villi hanging in a pool of maternal blood. The chorioallantoic placenta of rodents and Lagomorphs (rabbits) is the complex hemoendothelial type which consists of closely juxtaposed and highly modified fetal and maternal cells, permeated by a labyrinth of blood sinuses. An even more significant difference between the two types is that man has only the chorioallantoic placenta, whereas the rodents and the lagomorphs have a yolk-sac placenta as well. In man, once the chorioallantoic placenta has formed, most if not all, drugs reach the fetus by this route. In the rodents, often used as test animals, the presence of two types of placentae in the same animal means that the drugs might reach the embryo in two different ways, and it seems probable that in the earliest most vulnerable stage, the drugs that enter the embryo do so predominantly via the yolk-sac placenta6/....

The marked difference in the structure of the placenta between rats and humans, the alteration in metabolism at lower dosages, and the recognized higher susceptibility

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6/ "The Testing of Chemicals for Carcinogenicity, Mutagenicity and Teratogenicity," Minister of Health and Welfare, Canada, 1973.

of the rat to angiosarcoma, must all be taken into account in interrpeting Maltoni's results at extremely high concentrations. The highly idealized scheme (Figure 1) may serve to highlight some of the complexities of these factors.

2. TERATOGENIC EFFECTS

The landmark study of the teratogenic potential of VCM remains the industry-supported study by John et al., first reported in part at the 14th Annual Meeting of the Society of Toxicology in 1975. John and her co-workers subsequently published a detailed report of the work[7/], and again reinterated the findings at this most recent Symposium. The authors' published summary of this important study is as follows:

> ...Groups of pregnant CR-1 mice, Sprague-Dawley rats and New Zealand white rabbits were exposed to 500 ppm of vinyl chloride 7 hrs. daily during the period of major organogenesis. Subsequently, other groups of mice were similarly exposed to 50 ppm of vinyl chloride and rats and rabbits were exposed to 2500 ppm of vinyl chloride. While maternal toxicity was observed, vinyl choride alone did not cause significant embryonal or fetal toxicity and was not teratogenic in any of the species at the concentrations tested. Maternal toxicity was more prominent among mice than among rats and rabbits. Simultaneous exposure of some of the pregnant animals to vinyl chloride by inhalation plus 15 percent ethonol in the drinking water resulted in toxic effects greater than those associated with exposure to vinyl chloride alone in the three species. The maternal toxicity was enhanced to an extent greater than the embryotoxicity....(Emphasis added)

7/ John, J.A., Smith, F.A., Leong, B.K.J. and Schwetz, B.A. The Effects of Maternally Inhaled Vinyl Chloride on Embryonal and Fetal Development in Mice, Rats and Rabbits. Toxicol, Appl. Pharmacol. 39:497-513 (1977).

It should be noted that, to our knowledge. the conclusions reached by John et al. with regard to the teratogenic potential of VCM have not been seriously questioned and, in fact, have been confirmed.[8/]

Dr. John, in her presentation at the Symposium, discussed briefly the results of two additional studies of the teratogenic potential of VCM which have appeared in the recent literature. The first was a report of work carried out in Hungary,[8/] the findings of which were consistent with those reported by John et al. The second report, originating with the Institute of Hygiene and Occupational Health in Bulgaria, was available only in abstract form. Although sufficient detail was not presented in the abstract to permit a critical evaluation of the study, the reported results indicate a teratogenic response to much lower levels of VCM than would have been expected on the basis of the work of the John et al. or the Hungarian study. A complete assessment of this Bulgarian study would, therefore, seem essential, before it can be accepted.

Dr. John also mentioned the Symposium presentation of Hehir[9/]. As far as can be determined from the transcription of Dr. Hehir's talk, as well as what can be gleaned

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8/ Ungvary paper. Full citation

9/ Hehir, R., Cancer Induction Following Single and Multiple Exposures to a Constant Amount of Vinyl Chloride Monomer. Symposium Paper No. 5 (1980).

from a prepublication copy of the CPSA report[10], the study did not address teratogenesis. All F_0 animals were exposed before mating. Thus, although effects on reproductive capacity or genetic changes in the germ cells (e.g., dominant lethal effects) could possibly be manifest, ~~in the offspring,~~ true teratogenic events could not be revealed. It should be noted, however, that the F_0 exposure did not result in any alterations in the various parameters monitored in the F_1, F_2, and F_3 generations.

In summary, the most completely documented study of the teratogenic potential of VCM, viz., the study of John et al., reveals that under the conditions of the study, inhalation of VCM by pregnant rats, mice or rabbits was not embryo or fetotoxic, nor was it teratogenic even at concentrations sufficient to cause maternal toxicity. An additional published report basically confirms the latter conclusions, while results available only in abstract form from the Bulgarian literature purport to reveal a teratogenic effect for VCM at lower levels. Although this latter information is directly contradicted by the study of John and her coworkers, as well as by the Hungarian study, its full significance must await evaluation of the complete report.

10/ Hehir, R.M., Bierbower, G., Willigan, D.A., Kolaja, G., Marrs, G.E., Hinton, D.E., Dimmick, R.L. and Wiles, J.S. Toxicology, Carcinogeniity and Reproductive Effects of Single and Multiple Exposures to Vinyl Chloride in Rats and Mice. CPSC Prepublication Release, April 1, 1979.

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et al. was almost immediately questioned[15]. More recently, Haas and Schottenfield[16] have leveled severe criticisms at the Infante study, and the following is extracted from their paper:

> ...Analysis suggested that the number of fetal deaths per 100 conceptions was higher in the VCM-exposed group than in the comparison group. This difference was reported only for the period following vinyl chloride exposure. Adjustments removing women who were chronic aborters eliminated statistically significant differences. While the authors felt that these observations were likely to reflect a real difference in pregnancy outcome not attributable to either interviewer or patient recall bias, the conclusions were based on indirect sources of information and could not take into account the multiplicity of maternal factors known to affect pregnancy outcome. The study design precluded documenting in even the crudest manner the validity of pregnancy histories. Without such adjustments and validation, the inferences - - cannot be sustained and little light is shed on the possible association of abnormal pregnancy outcome with paternal occupational exposure to VCM....(Emphasis added).

Likewise, others have raised serious doubts regarding the validity of the conclusions drawn by the authors of the Infante et al. study. For example, Downs et al.[17] so completely discredited the study that their ultimate conclusion

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15/ Paddle, G.M., Genetic Risks of Vinyl Chloride Lancet 1:1079 (1976).

16/ Haas, J.F. and Schottenfield, D., Risks to Offspring from Parental Occupational Exposures. J. Occup. Med. 21:607-13 (1979).

17/ Downs, T.D., Stallones, R.A., Frankowski, R.F. and Labarthe, D.R., Vinyl Chloride, Birth Defects, and Fetal Wastage: A Critical Review. ~~Unpublished, Research Statistics, Inc.~~ (1977). Private Communication

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> ...It is disappointing to see an article of such poor quality -- published in The Lancet. The data are worthless, the analysis naive and the text inadequate and misleading in places....

and, after detailed point-by-point analysis of the study, presents the following conclusory statement:

> ...this paper is strewn with evidence of carelessness and incompetence and deserves -- no consideration whatsoever in weighing the question of whether there is or is not a genetic risk associated with exposure to VCM....(Emphasis added).

The foregoing reviews, two of which were available in 1977, completely rebut the scientific validity of the paper by Infante et al. in this matter. Absent a defense of this paper by the authors or their scientific peers, continued citation of this paper is inappropriate.

(3) Experimental Studies of Carcinogenicity and Other Toxic Manifestations For Any Level of Polyvinyl Chloride Exposure. These Effects Should Include, But Are Not Limited to, Mutagenicity, Teratogenicity, Embryo Toxicity, and Other Transplacental Effects As Well As Cytotoxic and Cytogenic Effects on Sperm Cells. To the Greatest Extent Possible, Complete Information Concerning the Industrial Source of the Polyvinyl Chloride, the Size and Characteristics of the Particles, and Exposure Levels or Concentrations of PVC and Residual VC Should Be Included for Each Study

The experimental studies of which SPI is aware show no carcinogenic or other toxic manifestations related to polyvinyl chloride exposure. Solid PVC is inert and the effects resulting from experimental exposure to PVC dust appear to be characteristic of nuisance dusts in general. They are limited to deposition of dust and have no adverse functional effects.

Two reports were presented during the course of the Symposium, i.e., the papers by Groth and Wagner. The paper by Frongia, et. al., cited as referenced no. 3 in the December 18, 1975 Notice, also deals with experimental exposure of test animals to polyvinyl chloride. In addition, SPI is aware of feeding studies conducted either with polyvinyl chloride resin, polyvinyl chloride copolymer resins, or low molecular weight fractions extracted from commercial PVC resins and/or copolymers. Two of these reports, one by Howard and one by Smith et al., are attached as Appendices ___ and ___. Other reports are in the files of the Food and Drug Administration (FDA) and efforts are being made to

obtain copies. As soon as they have been released to us, copies will be sent to the Docket Officer.

With regard to the papers presented by both Groth and Wagner, the specific nature and particle sizes of the samples used are not completely clear. It is essential that when written versions of their papers become available for study, these deficiencies be eliminated. For the present, we will only note that fine particle dispersion resins were used. As noted by Wagner, these may contain surfactants or other suspending agents. Hence, their use may result in a misattribution of the observed results to the wrong causative agent. As stated by Dr. Wagner, he has not been able to reproduce these results. Transcript at ____.

Nevertheless, taking the reports at face value, both studies appear to be consistent in demonstrating that exposure of experimental animals to respirable PVC dust results only in a low level of toxic response and in the retention of dust particles in the lungs with the development of macrophage aggregates. It is interesting to note that these experimental exposures (at least in the work of Groth with monkeys) did not result in impairment of pulmonary function. Although both authors considered that the dust induced a low-level pneumoconiosis[19/] in the exposed animals, their

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19/ Pneumoconiosis which literally means dust in the lung, can range from benign effects such as mere storage of particles in the lung to very severe effects such as fibrotic changes and death. It must be emphasized that as used in this response and by the speakers at the March 20-21 Symposium only lung storage and very minimal tissue response were seen. Fibrotic changes were not observed.

reports did not indicate the presence of fibrotic tissue which is observed in pneumoconiosis resulting from exposure to other substances such as silica.

The observations of Groth and Wagner appear to be quite consistent with the experimental work and observations reported by Frongia and his co-workers. Thus, it appears that in the experimental animals studied, exposure to respirable PVC dust particles results in retention of such dust particles for long periods of time, perhaps for the entire lifetime and the development of microphagic responses to these particles.

A major deficiency in all these studies is the absence of a control using an inert "nuisance" dust. Thus, the observations made as a result of exposure to PVC dust may be a characteristic response to all dusts, rather than a phenomenon attributed to PVC, per se.

As to the ingestion studies undertaken for the purpose of assuring the safety of PVC packaging materials, feeding either the whole resin or the low molecular weight (extractable) fractions showed no observed effects up to the maximum quantities used, i.e. in the range of 5%-10% of the animals' diets. In this connection, one other study might be mentioned, i.e., that conducted by CIVO/TNO in Holland, a copy of which is attached as Appendix ___. It is mentioned here only because a porous PVC powder was incorporated into the animals' diets as the vehicle to carry vinyl chloride

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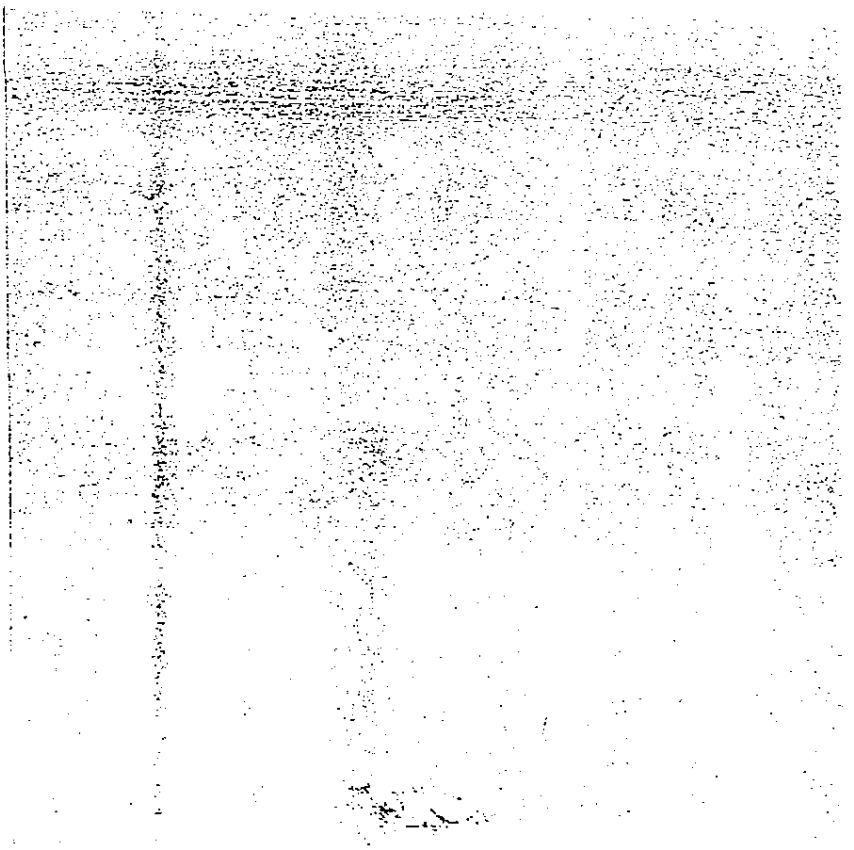

(4) Epidemiologic Studies of Either Vinyl Chloride or of Polyvinyl Chloride (i.e., cohort, cross-sectional, or case-control)

ecause of the importance of this area of informa-
Society postponed preparing responsive commentary
recent Conference to Reevaluate the Toxicity of
loride, Polyvinyl Chloride and Structural Analogs
held. Prior to this Symposium it had been specu-
at, perhaps, some new epidemiologic data or informa-
ht be presented concurrently with the industry-spon-
esentation of Dr. W. Clark Cooper. This, of course,
happen. In fact, it is The Society's view that
new in this area was presented at all.

However, because of the Agency's interest in the
area, SPI concluded that a detailed review of the
g epidemiology would be in order and appropriate for
with this OSHA Docket in response to the request for
formation. Accordingly, The Society has contracted
complete analysis of all the relevant epidemiologic
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(6) Mutagenicity Study Results of Vinyl Chloride or Polyvinyl Chloride As Measured By Analysis of Human Body Fluids, e.g., Direct Mutagenic Testing With Peripheral Blood Lymphocytes, Non-Disjunction In Humans With YFF Sperm Test And *In Vivo* Cytogenetics

It has been demonstrated that if mutagenic effects occur as measured by circulating lymphocytes, they were the results of high exposures; the measured effects have not been permanent changes since they were reversible. The effects did not occur at lower levels of exposure. The clinical significance is not known.

The attached report by Hansteen, Hillestad, This-Evensen and Heldaas is extremely important. Appendix ___. It indicates that the mean chromosome-breakage frequency which was significantly higher than controls when analyzed in 39 workers in 1974, was found on subsequent reexamination 2-2.5 years later to be no higher than the controls. Hence, what ever "effects" may have been measured and whether they were related to high levels of exposure to vinyl chloride *per se*, the "effects" reverted to normal when exposures to vinyl chloride were reduced. It is our understanding that similar results on a similar study are being prepared for publication by ICI in England and that they will supply a copy of the manuscript when available

Picciano *et al*. found no effects in a study on men who probably had lower levels of exposure than those above. Appendix ___. They summarized their data as follows:

> ...This report presents cytogenetic findings from a group of 209 workers employed for up to 28 years in the manufacture of vinyl chloride monomer at the Texas Division of Dow Chemical U.S.A. Cytogenetic evaluation results from this group were compared to results found in examination of individuals being considered for employment. Statistical analyses were performed on a group basis for chromatid aberrations, chromosome aberrations and proportion of abnormal cells; no statistical difference of significance was found between the two groups. Comparison of these results with reported studies suggests that the level of cytogenetic aberrations in vinyl chloride workers is probably related to the length and level of exposure, and that risk of adverse genetic effect can be avoided in controlled, minimal-exposure environments....

Fabricant attempted to summarize the mutagenic studies on vinyl chloride at the Symposium. This report merely reviewed the collected, previously-published information; nothing new was presented.

The author pointed out that genetic anomalies resulting in infant mortality increased from 5% in 1915 to 15% in 1965. She alleged that 33% of pediatric hospital admissions are due to genetic defects and that 80% of all clinical mental retardation in the U.S. arises from genetic causes. She speculates that these observations are due to "an environmental component" creating birth defects. No mention is made of improved diagnostic tools, however.

This author also relied on the discredited paper by Infante et al. This publication (reference 12 of the December 18 Notice in the Federal Register) alleging reproductive effects in wives as a result of mutagenic changes in husbands who were exposed to vinyl chloride has been dis-

credited because of faulty methodology. See Appendicies ___, ___, and ___. The faulty nature of this study has been repeatedly demonstrated to OSHA and, therefore, absent a defense of this study by the authors or their scientific peers, it should no longer be cited.

(7) Body Burden Measurments
of Vinyl Chloride In Humans

The meaning of this specific request for information is not clear. Being a poorly soluble gas, vinyl chloride does not accumulate from chronic exposure but, rather, is rapidly exhaled after exposure ceases. Hence, there can be no body burden in the usual manner which the term is applied to accumulation of heavy metals, poly-halogenated organic compounds or radiation.

Baretta, Stewart and Mutchler studied this subject and reported on "Monitoring Exposures to Vinyl Chloride Vapor: Breath Analysis and Continuous Air Sampling." American Industrial Hygiene Association Journal, Vol. 30, November-December 1969. The data in this study clearly shows rapid decay in the expired air in industrially exposed employees and laboratory subjects.

Several published metabolic studies on laboratory animals and human subjects also indicate rapid excretion of vinyl chloride in expired air. This, again, is consistent with the high volatility and low solubility of vinyl chloride gas.20/

20/ Ref. coming from T.R.T.

(8) For Operations Involving Polyvinyl Chloride, the Types of Resin in Use, the Concentration of Vinyl Chloride Trapped in the Resin, and the Concentration of VC and PVC Dust in the Atmosphere Where Individuals Are Working. This Information Should Include Estimates of the Particles Sizes and Concentrations of Particles That Fall Within the Respirable Range

and

(9) In PVC Bagging and Milling Operations, Atmospheric Levels of PVC and VC, Monitoring Devices Used to Detect VC, and the Type of Respirator Protection Program for Individuals Working in These Operations. This Should Include the Sensitivity and Validity of the Analytic Techniques in Use

Information supplied below is likely to create confusion if used out of context. Therefore, operations involving polyvinyl chloride are broken down into the following sections:

1. Manufacture of PVC
2. Distribution
3. Compounding
4. Fabrication into semi-finished materials
5. Conversion of semi-finished materials to finished products

Past regulatory effort on the part of OSHA has resulted in the promulgation of regulations that covered resins containing any amount of contained vinyl chloride and materials that contained little or no vinyl chloride monomer; therefore it appears necessary to call OSHA's attention to all

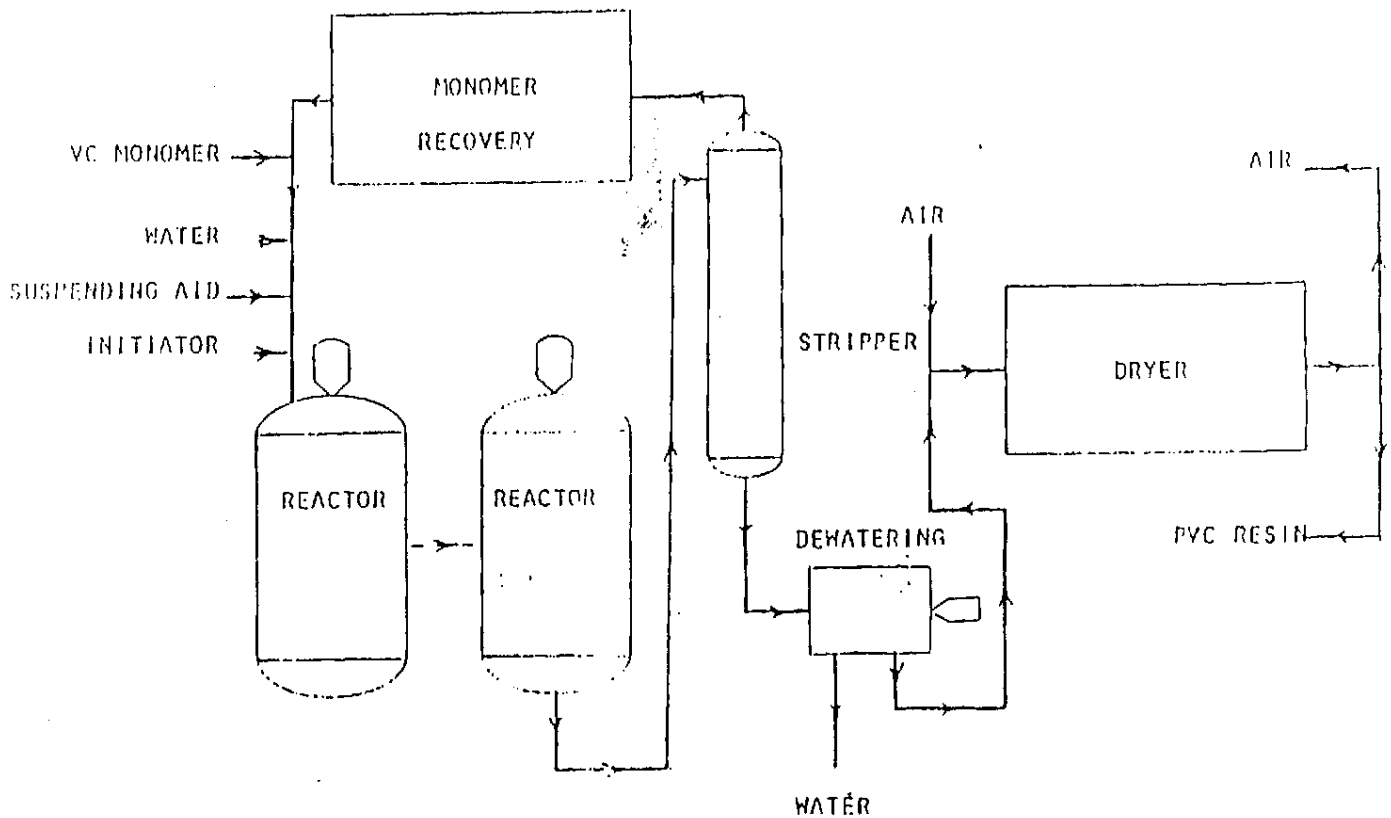
aspects of the industry.

The manufacture of synthetic resins from vinyl chloride and other monomers involves reacting these monomers in agitated pressure vessels in the presence of catalysts in such a way that these liquids and/or gases are converted to solid resins. A considerable amount of heat is generated by the reaction. This is removed by cooling the vessel. As the monomer is converted to polymer during the reaction, the rate of reaction slows down. The unconverted monomers are removed from the reacting mass by heat and vacuum and the resin (PVC) is recovered as a dried powder or as a latex or solution. The polymerization reaction may take place in pure monomer, in a solution, in a water-monomer emulsion or in a water-suspension of monomer. The nature of the polymerization process determines the nature of the subsequent recovery process and the nature of the resins particles produced.

Currently there are four basic vinyl chloride polymerization techniques;

1. Suspension
2. Emulsion
3. Bulk
4. Solution

Suspension polymerization is the major process used for the manufacture of PVC resins and is used for about 82-85% of U.S. production (Figure 1). It involves the charging



SUSPENSION POLYMERIZATION PROCESS

FIGURE 1

of one or two parts water and one part vinyl chloride monomer or co-monomer mixture to an agitated reactor along with initiator and suspending agents. The mass is reacted at 50 to 65°C until about 85-90% of the monomer is converted to resin. The resin-water mixture is then heated, sometimes under vacuum, until the unconverted monomer is substantially removed. The resin is then removed from the water and dried in rotary, flash or fluid bed dryers by exposure to heated air. The dried resin is transferred to storage silos prior to shipment in bulk containers or in paper bags. If only vinyl chloride monomer is reacted the product is homopolymer PVC. If a monomer such as vinyl acetate is mixed with the vinyl chloride then a co-polymer PVC is produced.

Resin products of the suspension resin process are many and varied in terms of molecular weight, composition, particle size, monomer retention, heat stability and ultimate use. A general description of the various grades of resins follows:

(a) General purpose homopolymer for flexible materials such as shower curtains and wire insulation are porous, large particle (10 micron or more diameter) size, high molecular weight resins with good heat stability and low monomer retention characteristics. These resins contain essentially no particles less than 10 microns in diameter and the residual monomer content is in the range of 0 to 25 ppmw.21/ Particle porosity is a critical property.

21/ Particles 10 microns or larger in diameter are considered non-respirable.

(b) Homopolymer resins for pipe manufacture are dense, large particle size (~100 microns), high molecular weight resins with good heat stability. Monomer retention characteristics are medium to low. These resins contain essentially no particles less than 10 microns in diameter and residual monomer content is in the range of 0 to 30 ppmw. Generally the lower the molecular weight the higher the monomer retention. Particle density is a critical property.

(c) Homopolymer resins for rigid extruder shapes and calendered rigid sheeting are dense, medium particle size (80 microns in diameter), medium molecular weight resins with reasonable heat stability and medium monomer retention characteristics. These resins contain essentially no particles less than 10 microns in diameter and the residual monomer content ranges from 0 to 50 ppmw. Particle density is desirable and porous particles are difficult to produce.

(d) General purpose copolymer resins for rigid sheeting, molding and flooring are medium particle size (80 microns in diameter), glassy to low porosity, low to medium molecular weight, and high in monomer retention with poor heat stability. Comonomer content ranges from 0 to 15%. The monomers most often used are vinyl acetate and vinylidene chloride. These resins contain essentially no particles less than 10 microns in diameter and residual monomer in the range of 100 to 200 ppmw. The poor heat stability coupled with the glassy particles make vinyl chloride monomer removal difficult. Copolymer resins offer ease of fabrication and have the ability to take up high loadings of fillers and pigments.

(e) Copolymer resins for coating applications are low molecular weight, medium particle size (75 microns), glassy non-porous particles, poor in heat stability and high in monomer retention. Co-monomer content ranges from 0 to 40%. These resins contain few particles less than 10 microns and residual vinyl chloride monomer contents of 25 to 100 ppmw.

(f) Plastisol additive resins for dispersion resin fabrication are medium molecular weight, small particle size (25 microns in diameter), low in particle porosity, and medium in heat sta-

bility materials. The addition of these resins to a dispersion resin plastisol reduces the plastisol viscosity and reduces the product cost. The ability to perform uniformally in a plastisol is critical. These resins contain appreciable quantities of particles smaller than 10 microns in diameter and contain 0 to 25 ppmw of residual vinyl chloride monomer.

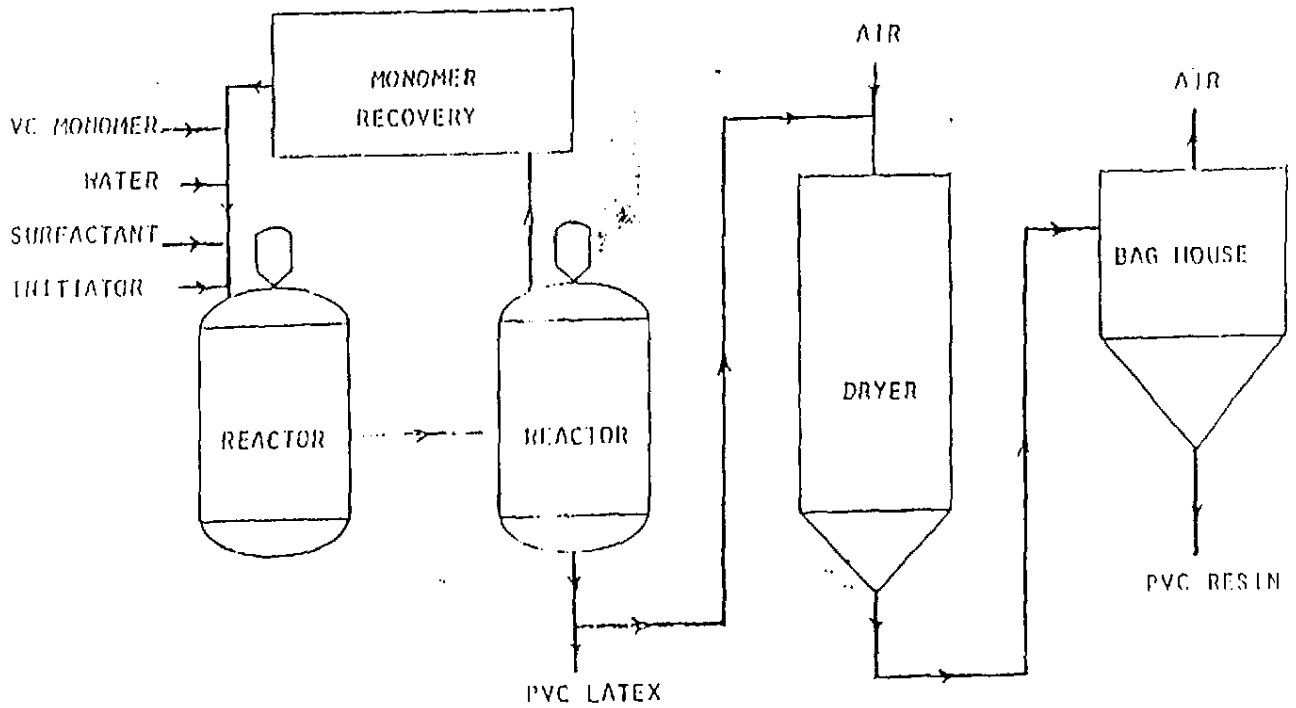
Suspension process plants are generally meeting the permissible personal exposure limit of 1 ppmv TWA_8 imposed by the OSHA Standard but are having difficulty meeting the 5 ppmv ceiling value without the use of respirators. Certain tasks, such as maintenance, cleaning and correcting process upsets, involve personnel exposure to brief periods of high vinyl chloride concentrations. These personnel are protected by continuus air-supplied respirators. Elimination of all use of respirators cannot be considered a realistic requirement.

Suspension PVC, except for plastisol additive resins, presents no hazard from exposure to respirable dusts since these resins contain essentially no particles less than 10 microns in diameter. Indeed, except for the plastisol additive resins, the use of cyclone collectors on resin dryers and resin transfer systems obviates the presence of such particles in suspension resins, i.e., such particles are lost.

Emulsion polymerization is the second most widely used process for the manufacture of PVC resins and amounts to 10-12% of total U.S. production. One of the important

things to understand about emulsion polymerization is that it is not a single process but a family of processes, each producing specialized products that are defined or specified in terms of performance in a particular application. In the interest of brevity only the two major process families, the water soluble initiator systems and the oil-soluble initiator system, will be discussed. (Figure 2).

In the water soluble initiator system one to two parts water, one part monomer, 0.01 to 0.03 parts surfactant and water-soluble initiator (a redox system or a persulfate salt) are charged or fed to an agitated reactor and reacted at 30 to 60°C to form a latex emulsion. The reactor agitation must be sufficiently vigorous to emulsify the monomer-water mixture but not so vigorous that the latex is destabilized. When 80 to 95% of the monomer is converted to polymer the latex may be gently stripped of the unconverted monomer with heat and vaccum or it may be subjected to a second initiator treatment and reacted to essentially 100% monomer conversion. The product of this polymerization may be simply filtered and shipped to consumers as a latex for use in the manufacture of coatings, mastics, laminations, and the like, or the polymer may be recovered as a dry resin. Recovery techniques vary. The most commonly used is to spray-dry the latex, though some resins are recovered by coagulating the latex and dewatering with subsequent drying of the coagulum (resin).



EMULSION POLYMERIZATION PROCESS

FIGURE 2

In the oil soluble initiator system one part monomer containing an organic peroxide is emulsified in one to two parts water containing 0.01 to 0.03 parts surfactant. The resulting emulsion is reacted at 30 to 60°C to form a latex. From this point onward the oil soluble initiator system is similar to the water soluble initiator system.

The choice of process depends to a great extent on the ultimate use of the resin. If resin particle size is critical the oil soluble initiator system is preferred. The resin particles formed during emulsion polymerization range in size from 0.05 to 2 microns. In the course of recovery and drying these may be agglomerated to particles as large as 30 microns. For some uses the agglomerates may be ground to a median particle size of about two microns. The small particle size results in rapid loss of residual vinyl chloride so that the resin contains only about 1 ppm free monomer. Because of handling problems nearly all the resin is bagged. In this process, the small amount of monomer retained easily escapes before the resin arrives at a fabricating plant.

Resin products of the emulsion process are more difficult to list because most products are sold on a performance basis as opposed to suspension products which are sold largely on specification and price. A rough classification is as follows:

(a) Plastisol resins are the major emulsion process products. These are very small particle

size (2 to 3 micron diameter), non-porous, very high molecular weight, 100% vinyl chloride resins with good heat stability and low monomer retention characteristics. These resins consist of particles less than 10 microns in diameter, contain significant amounts of surfactants and about 1 ppmw of residual vinyl chloride monomer. When stirred into approximately 60 parts of plasticizer per hundred parts resin, these resins yield a viscous liquid plastisol which, when baked, fuses to a flexible vinyl plastic.

(b) Foam resins are substantially the same as the plastisol resins except that they are medium molecular weight instead of high. The lower molecular weight yields a plastisol which fuses near the temperature at which a blowing agent yields up its gas. This is how a stable plastic foam is formed.

(c) Organosol resins are a special variety of plastisol resin primarily used for metal coating. If a high molecular weight PVC homopolymer dispersion resin is very finely ground and the remaining agglomerates are loosely bound together it can be ground further with ketone, naphtha, pigments, stabilizers and adhesion promoters to yield a liquid coating material. This organosol is coated on metal and baked to provide a tough, abrasion resistant coating.

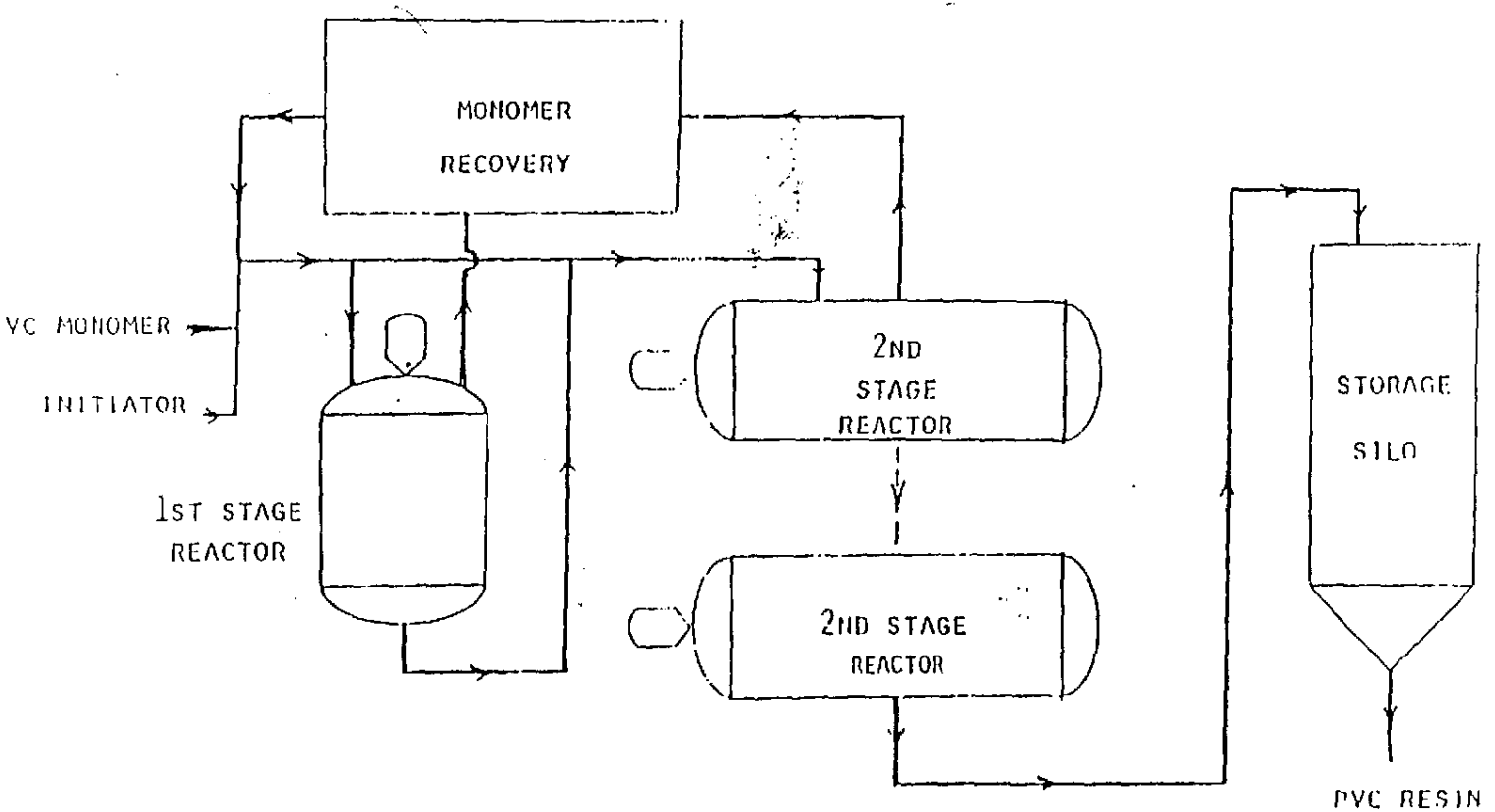
(d) Specialty resins are an assortment of materials that make use of the flexibility of the emulsion process for their manufacture. These are made from vinyl chloride in combination with other monomers. The resins are recovered from the latex by coagulation and subsequent drying. Uses of these materials range from film for food packaging to modifiers for other resin fabrication. Further characterization of these materials is not possible and they are mentioned here only to call attention to the fact that these important resins are impacted by vinyl chloride and polyvinyl chloride regulations.

(e) Latexes, too, are an assortment of materials generated by the flexibilty of the emulsion process. These are liquid materials containing 40 to 50% resin solids emulsified in water. Latexes containing resin solids high in vinyl chloride content are usually formulated with plasticizers and solvents and applied to a sub-

strate. The substrate is heated or baked to yield a resin film. Latexes containing resin solids low in vinyl chloride content will yield a resin film when the latex coating is simply air dried. These latexes find major use in latex paints, impregnants, mastics and adhesives. Since both types of latexes are used as liquids there is obviously no possibility of PVC dusts. Depending on the latex produced, most PVC latexes contain less than 10 ppmw of residual vinyl chloride monomer. This monomer is released slowly and employee exposures in subsequent formulating and use is rarely over 0.05 ppmv.

As is the case with suspension PVC process plants, emulsion process PVC plants are generally meeting the OSHA permissible exposure limit of 1 ppmv TWA_8 for employees. These plants, too, however, are experiencing difficulty meeting the ceiling limit without reasonable use of respirators. The manufacture of dispersion PVC resins represents a source of respirable PVC dusts and dust respirator use is usually required in dusty locations such as bagging.

Bulk polymerization is the third major process in terms of volume for the manufacture of PVC resins but accounts for only about 5% of U.S. production. (Figure 3). The process involves the charging of vinyl chloride monomer and initiator to a first stage polymerizer where about 10% of the monomer is converted to polymer. This batch is then transferred to a second stage polymerizer where additional monomer, and sometimes initiator, are added. The polymerization is continued until about 80-85% of the monomer is converted to polymer. The unreacted vinyl chloride



BULK POLYMERIZATION PROCESS

FIGURE 3

is removed by heat and vacuum and the finished resin product transferred to storage bins for later shipment to fabricating plants. The absence of water in the polymerization stage eliminates the need for the drying step.

The advantages of the bulk process are its simplicity, the uniformity of the resin particle size, the high porosity of the resin particles, the purity of the polymer (no soaps or suspending aids) and the granular, low dustiness of the product. The disadvantages are: less flexibility in product mix (homopolymers only) than the suspension process and poorer removal of residual monomer. These bulk process resins are competitive with suspension process PVC homopolymers.

Bulk process PVC resins are used in applications where clarity of the finished plastic, uniform resin particle size and high resin particle porosity are desired. A simple classification of their uses is as follows:

(a) Rigid and flexible plastic materials produced by extrusion and calendering requires resins with large porous particles (100 microns in diameter), good heat stability and low monomer retention. These medium molecular weight homopolymer resins contain essentially no particles less than 10 microns and the residual VC monomer content is less than 50 ppmw.

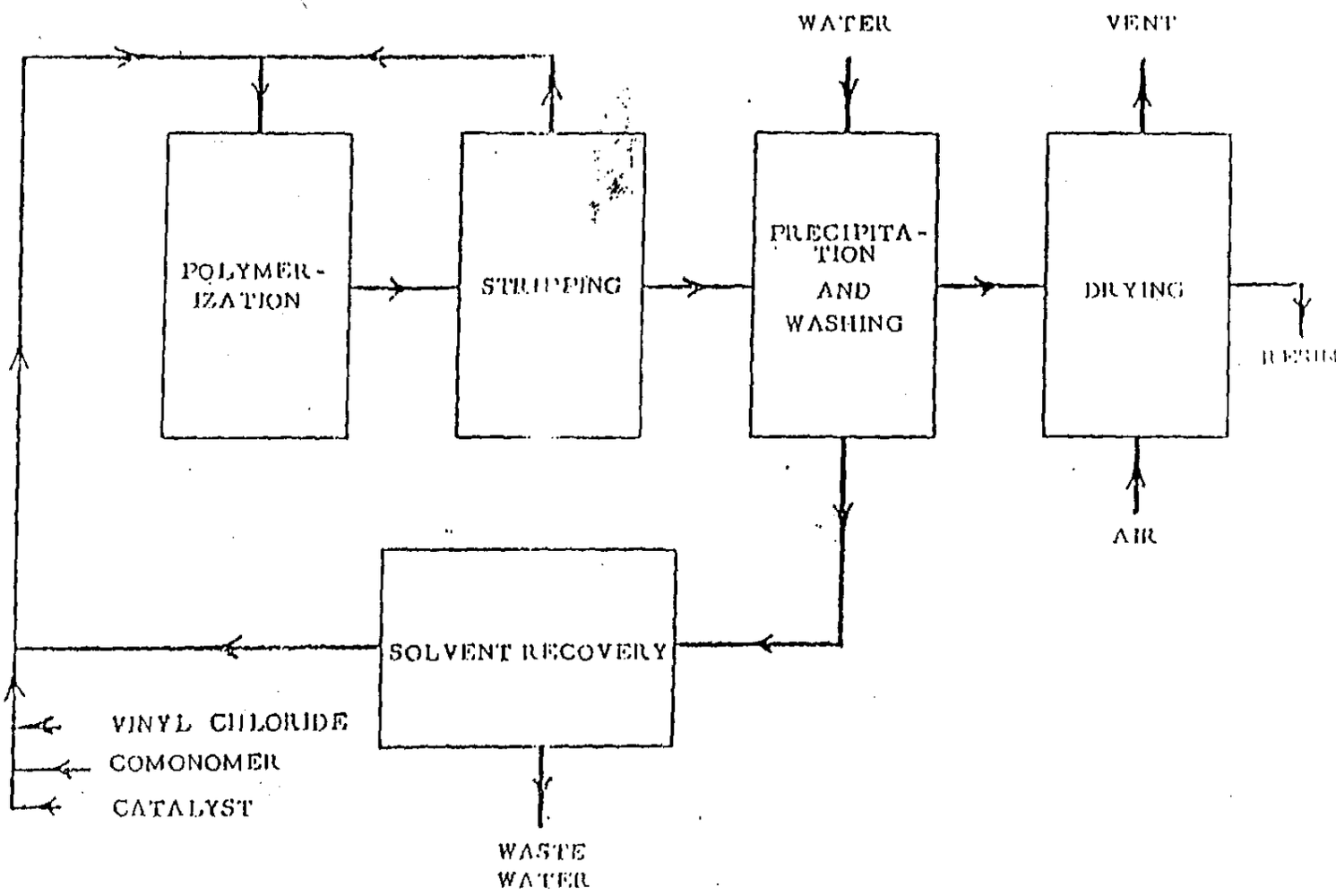
(b) Rigid plastic moldings, plastisol additive resins and powder coatings are made from low molecular weight homopolymers with a particle size of 75 microns. Particle porosity is good and monomer retention is low. There are few particles less than 10 microns in diameter and residual vinyl chloride content is less than 50 ppmw.

Bulk process plants have the same general types of personnel exposures to vinyl chloride noted for suspension process plants.

Solution polymerization is a process unique to Union Carbide Corporation and accounts for about two percent of the total resin produced. (Figure 4). Vinyl chloride monomer, co-monomer, solvent and initiator are fed to a continuous reactor system. The polymer formed is soluble in the reacting mass so that the reactor product is a viscous resin solution. This solution is distilled to remove the unconverted monomers and the resin is recovered by treating the resin solution with water and drying the product. The resin particle is very porous, is always a copolymer, is free of soaps and suspending agents, has a median particle size of 75

FIGURE 4

SOLVENT VINYL RESIN PROCESS



microns and contains less than 0.2 ppm residual vinyl chloride. Solution process PVC resins are very often confused with suspension process resins for solution application. Molecular weight of these resins ranges from low to very low to achieve solubility in solvents. Essentially all these materials are used for coatings in combination with other resinous materials.

The solution PVC resin process because of its nature exposes personnel to vinyl chloride concentrations below 0.5 ppmw. The resin contains essentially no particles less than 10 microns in diameter.

In addition to the resins produced by the four basic processes there are resins which are chemically modified in a second operation after the resin has been produced. The major products in this area is chlorinated PVC. In the coatings area copolymer resins are often modified through reactive sites in the co-monomer. These materials are mentioned only to note their existence and to point out that the very nature of chemical modification and subsequent processing removes all possibility of their release of vinyl chloride in subsequent applications.

Distribution of PVC resins poses some potential for personnel exposure to vinyl chloride monomer and to polyvinyl chloride. The structure and the economics of the distribution system have acted to cause such exposures to be minimal except for certain special situations.

Suspension and bulk process PVC resins, except for plastisol addition powder coating, solution coating and export sales move from the producing plant to the user via bulk carriers such as rail cars (containing approximately 150,000 pounds) or hopper trucks (containing approximately 35,000 pounds). These carriers are loaded via gravity from overhead bins or by pneumatic conveyor. The carrier is sealed during transit. On arrival at the delivery site, the carrier is unloaded by pneumatic conveyor to a storage silo. There is some vinyl chloride monomer emitted during the loading and unloading process but personnel exposure is well below the OSHA Standard "action level". Monitoring of this operation when the resin contained 800 ppmw of residual vinyl chloride monomer showed personnel VCM exposures of approximately 1 ppmv TWA_8. Although there is no recent data, with current residual VCM levels of approximately 50 ppm, one would expect personnel exposures to be down around 0.1 ppm TWA_8. There is some resin dusting and spillage in the loading and unloading process but the relatively large particle sizes and remote contact by personnel obviate any potential hazard.

The bagging of suspension and bulk process resins in this fashion is highly automated and messy, but personnel exposure to dusts or VCM are negligible. Resin is delivered to the packaging machine via gravity or pneumatic conveyor. The packaging machine operator inserts the filling tube into a filling valve-type kraft paper bag and actuates the machine

to fill the bag. The filled bag drops off the filling tube to a conveyor and the operator repeats the operation with another bag. Filled bags are automatically or manually stacked on pallets which may be stored in a warehouse awaiting shipment or may be loaded on a truck or railcar immediately.

When the filled bag drops off the packing machine a small puff of resin and air is emitted from the bag valve as it closes. Subsequent handling of the bag causes some shifting of resin out of the valve. There are also faulty bags which may break on filling. Thus, the resin bagging area is usually messy. However, monitoring conducted in these areas indicates personnel vinyl chloride exposures are less than the OSHA Standard "action level." Dust measurements for suspension and bulk resin bagging show less than 1 mg/m^3 respirable dust.

Bagging and storage of suspension and bulk process resins causes a significant reduction in the residual vinyl chloride content of the resin. Tests of moderately porous medium molecular weight resins shows a reduction of over 50% in free monomer after one week. Handling and transport of suspension and bulk PVC resin in bags via truck or rail car appears to present no unusual hazards if normal work space ventilation standards are met in storage, loading and unloading resins.

Except for some special situations where bulk transport or fiber drums are used, essentially all emulsion pro-

cess PVC resins are packaged in kraft paper multi-wall bags. The bagging operation is essentially the same as that described for suspension and bulk process resins. Vinyl chloride exposure is less than the OSHA Standard "action level." The NIOSH study by Mr. J.H. Jones in 1974 indicated that exposure is not likely unless it comes from emissions in adjacent operations.[22/] Dust exposure is potentially a problem due to the resin's small particle size but local ventilation can control this readily. Current dust monitoring shows respirable dust less than 5 mg/m^3.

The storage and truck shipment of emulsion PVC resins offer minimal vinyl chloride exposure opportunities for personnel.

Warehouse and closed truck vinyl chloride monitoring show levels well below 0.5 ppmv vinyl chloride in the air.

Solution process PVC resins are also packaged primarily in kraft paper multi-wall bags. Bagging is essentially the same as described for suspension resins. The NIOSH study in 1974 indicated vinyl chloride exposure to baggers of 0 to 0.7 ppmv and total dust of less than 2 mg/m^3.[23/] Vinyl chloride exposure currently is about 0.1 ppmv with no change in total dust exposure. Respirable dust is about 0.1 mg/m^3.

Monitoring of storage and truck shipment of solution process PVC resins usually shows undetectable amounts of

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22/

23/

vinyl chloride monomer

Polyvinyl chloride latexes are most often handled and shipped in tank cars or trucks and in fifty-five gallon drums. There is some emission of vinyl chloride during loading and unloading operations but, if the latex contains 10 ppmw residual vinyl chloride or less, the personnel exposures are less than 0.5 ppmv. Dust is not a problem with latex shipments.

Compounding a PVC resin or latex means the mixing of that material with pigments, stabilizers, plasticizers, fillers and other additives to yield an intermediate material for subsequent conversion into finished or semi-finished products. In major plastics operations this is simply a single process step in a large integrated factory, but in the specialty resin area, as well as with small plant operations, a compound is produced by one plant and is subsequently shipped in a container to the user. Thus, in terms of regulation, these materials are classified as polyvinyl chloride. Often, however, the properties of the material are completely dissimilar to the PVC resin raw material, i.e., the vinyl chloride monomer content is diluted or reduced by heating and dustiness is reduced sharply or eliminated completely. Some examples are pelletized PVC compounds, powder blends, organosols, plastisols, lacquers, dry blends, and latex paints.

The purpose of compounding is to combine the resin and additives into a homogeneous state suitable for further

processing. The level of compounding ingredients employed for PVC is substantially higher than for most plastics. Resin content of a compound may vary from 99% for rigid sheeting to 15% for floor tile. Some compounding ingredients introduced in PVC fabrication are as follows:

(a) Plasticizers are high boiling temperature esters of phthalic acid, adipic acid, azelaic acid, phosphoric acid and so on. Epoxidized oils, epoxy resins, and polyester resins are also used.

(b) Heat stabilizers are compounds of lead, barium, cadmium, tin and zinc. Epoxies and phosphites are also used.

(c) Fillers consist of clay, talc, mica, asbestos, calcium carbonate, titanium dioxide, diatomaceous earth and barytes.

(d) Pigments may be inorganic compounds, such as titanium dioxide, chromium oxide, ultramarine blue or molybdate orange, or they may be organic compounds, such as phthalocyanine, quinacridone and benzidine salts.

(e) Modifying resins improve processing characteristics and impact resistance. These are acrylates, ABS, and chlorinated polyethylene resins.

(f) Lubricants make subsequent processing easier. Some of these are waxes, stearic acid and metal stearates.

(g) Light stabilizers provide ultra-violet light resistance. Examples are benzotriazoles or benzophenones.

(h) Fungicides give resistance to fungal attack. Materials commonly used are amines, arsenates and organotins.

(i) Flame retardants, such as antimony oxide and the boranes, are used where plasticizer content is high.

(j) Anti-static agents reduce dust and dust pickup. These are often amine compounds.

(k) Brighteners yield a whiter, clearer film.

(l) Anti-oxidants, such as bisphenol A, are sometimes used.

Additionally, particularly in the coatings area, there are specialized additives such as surfactants, pigment wetting aids, solvents, and diluents.

These compounding ingredients and additives are mentioned in some detail to show the difficulty of isolating causative agents if an employee health problem is believed to exist in the PVC fabricating area. It is certainly a mistake to attribute dust problems solely to PVC dust and toxic vapor problems solely to vinyl chloride monomer.

Compounding PVC resins for subsequent fabricating via calendering, extrusion or molding involves two basic steps; dry or powder blending followed by melt compounding. The choice of equipment is important because variations in the homogeneity of the resin compound may cause serious deficiencies in processing and in the finished product. The calendering, extrusion and molding operations involve large scale operations with suspension and bulk process PVC resins which are almost always handled in bulk. Resin is charged from a bulk silo to a weigh hopper and dumped into the mixer. Plasticizers are metered into the charge. Other additives are charged by similar techniques though small volume additives may be first mixed into a portion of the plasticizer. The mixer is closed and heat is applied externally or generated by the shear action of the mixer itself. The charge

is subjected to mixing and heat (approximately 200-250°F) until the mass is a dry powder or for some predetermined time. Gases from the charge are vented outside the work area. On completion of the dry or powder blending, the mix may be cooled and stored for subsequent use or charged directly to a high intensity mixer or to an extruder.

The mixers and/or the extruder melt the dry or power compound blend to secure a hot plastic mass. For calendering, the mixer or extruder charge is transferred to the calender when it is formed into flexible film or into rigid sheets as semi-finished products. For extruder products, the extruder may simply be fitted with a die, as is the case in the manufacture of pipe, to form the finished product. The industrial hygiene survey carried out by NIOSH in 1974 and 1975 indicated that vinyl chloride monomer exposures for this type of operation in the range of ND to 0.6 ppm.[24/] (See attached Table 33 from the NIOSH report). With the current low levels of residual vinyl chloride monomer in suspension and bulk process PVC resins, vinyl chloride monomer exposure is negligible.

Dust is a problem in calendering, molding and extrusion processing but as Mr. Jones points out in his NIOSH report the dust is probably not all PVC since fillers and other additives are used.[25/] Mr. Jones does not mention,

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24/

25/

Tab

Summary of Vinyl Chlor
—All Fabrication

Job	n
Calender Personnel	28
Compounding Personnel	78
Extrusion Personnel	58
Lab Personnel	18
Maintenance Personnel	10
Molding Personnel	16
Plastisol Dipping Personnel	40
Miscellaneous Personnel	20
Total of Personal Samples	268
Composite of All Area Samples	32

* $\bar{x}$ = TWA

5

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however, that plasticizer aerosols formed during processing also appear as part of the total dust measurement. (See attached Tables 30 and 32 from the NIOSH report along with flow sheets for calendering, pipe extrusion and flexible film extrusion).

Plastisol techniques for compounding and fabricating PVC involve the use of dispersion process PVC resins along with plastisol additive resins from the suspension and bulk PVC processes. The principal advantages to this fabrication technique and bulk PVC processes. The principal advantages to this fabrication technique are low investment in fabricating equipment and flexibility in changing from one product to another. A basic plastisol might consist of 100 parts dispersion process PVC resin, 55 parts dioctyl phthalate plasticizer, 5 parts epoxy plasticizer and 3 parts barium, cadium or, zinc liquid stabilizer. Heating the plastisol to 350-375°F fuses it into a flexible homogeneous plastic. In practice, however, the only time this simple formulation is used is to test resins. Additive resins are used to reduce cost, to alter the plastisol viscosity and to increase the hardness. Reactive resins, such as epoxies and acrylates, are added for hardness. Pigments are added for color and opacity. Anti-foamers reduce foaming during deaeration and fusion.

Plastisol preparation is carried out in a slow speed, unheated mixing vessel. Plasticizer is weighed or metered into the vat and followed by the requisite number of bags

Table 30

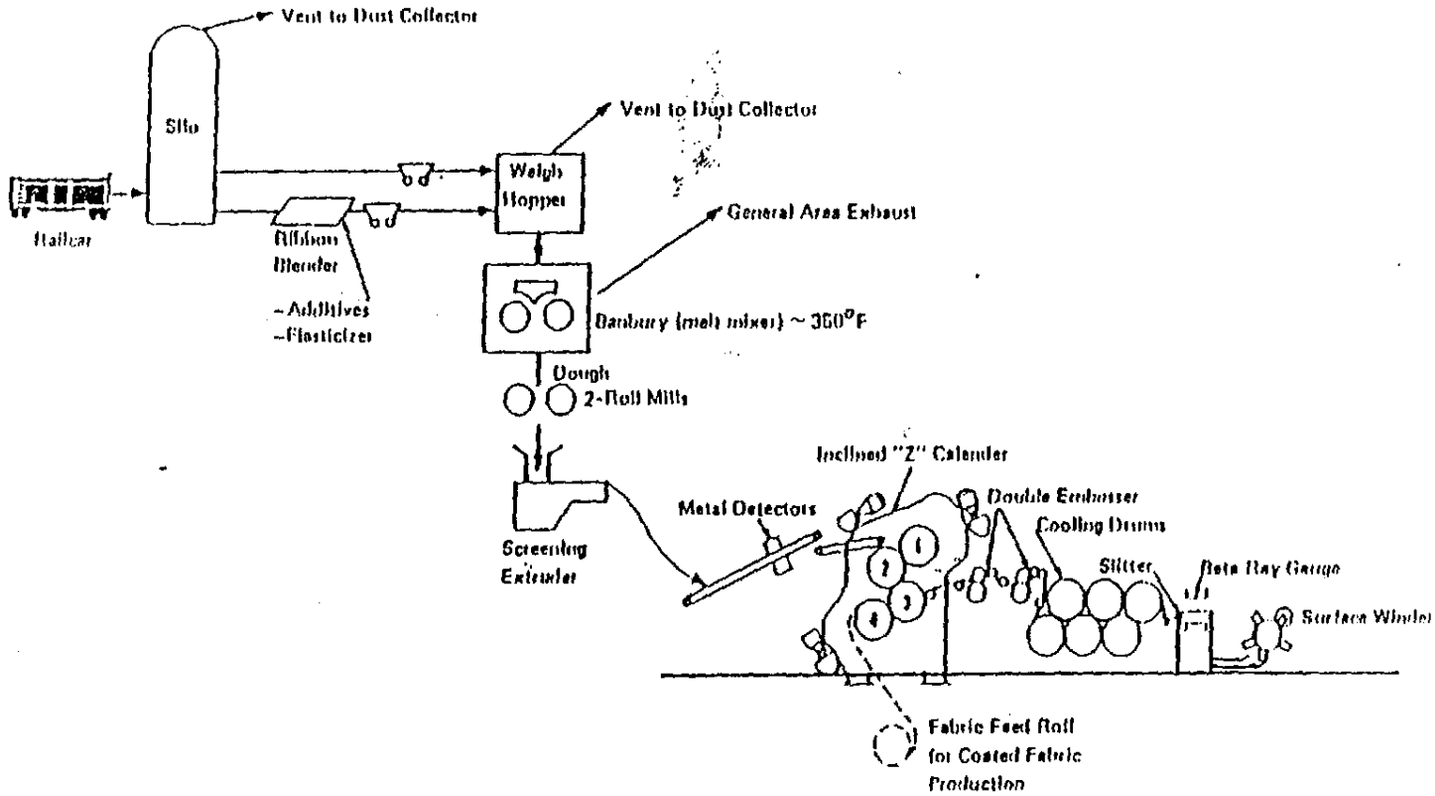
Polyvinyl Chloride Dust Sampling Data
Plant 1

Location	Dust Concentration mg/m^3
Near Blender	12.5
"	7.22
"	6.67
"	8.75
"	11.67
Near Mixer	10.0
"	6.06
Near Calender	11.67
"	8.33

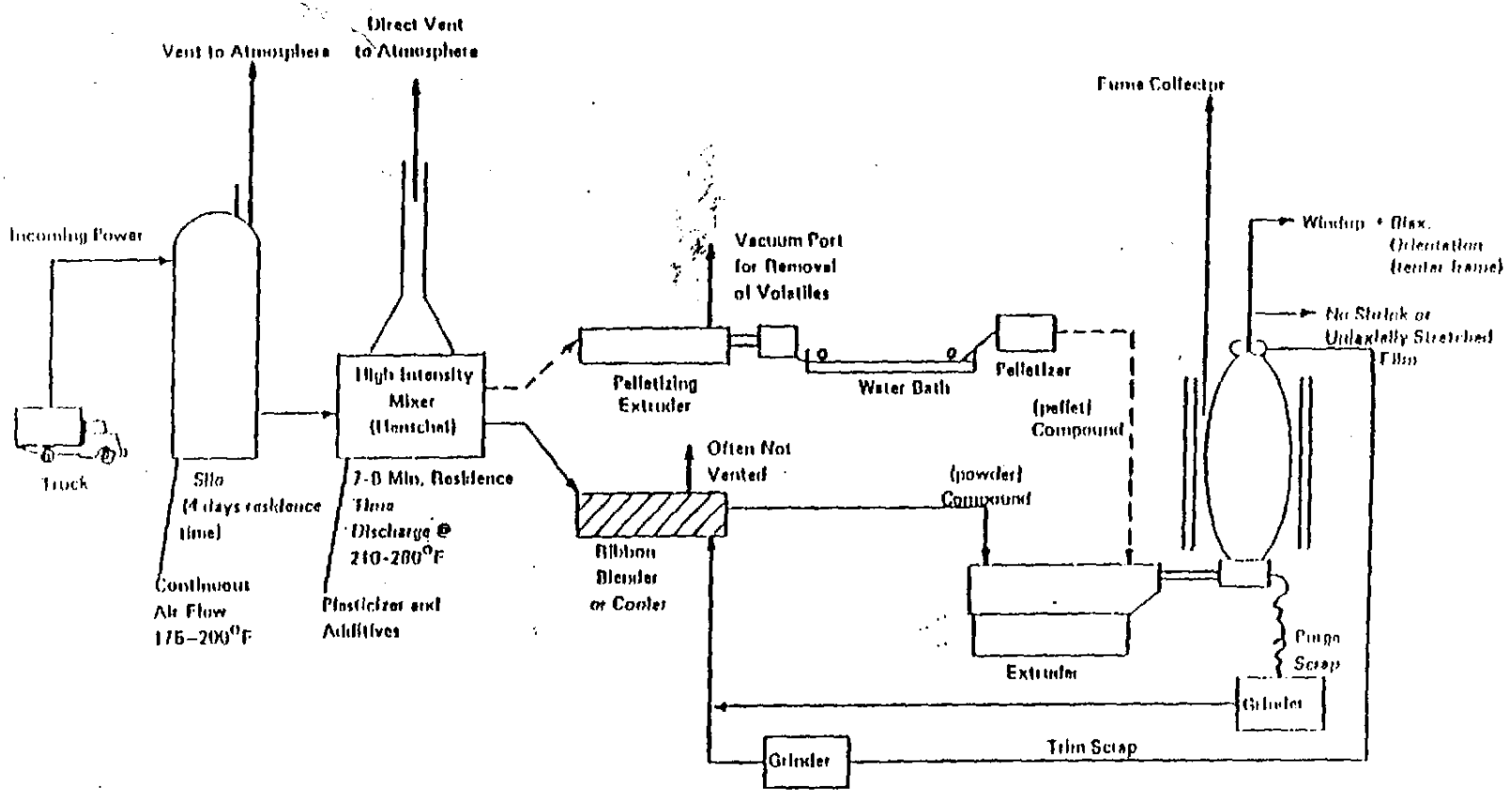
Table 32

Polyvinyl Chloride Dust Sampling Data
Plant M

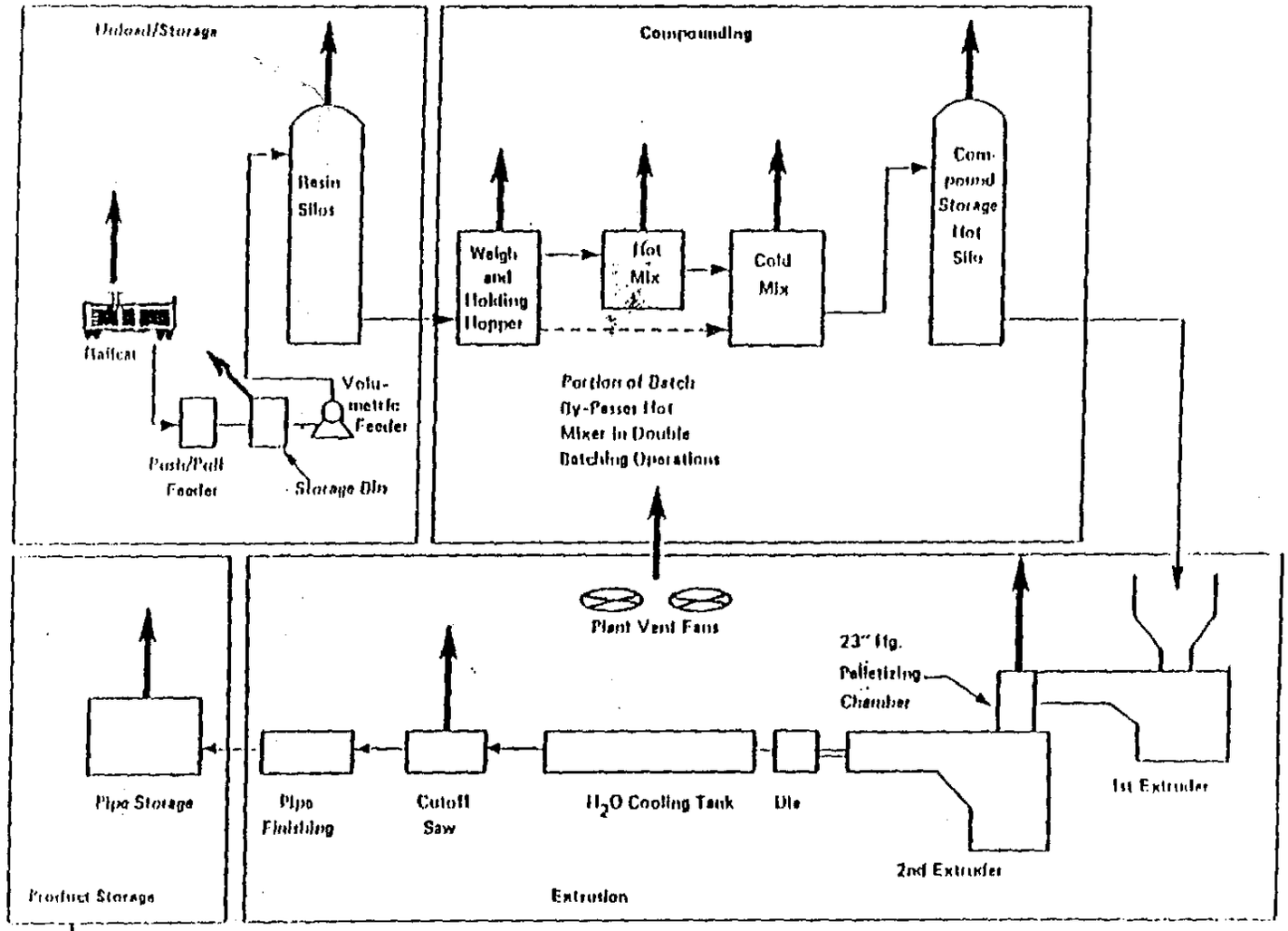
Location	Dust Concentration mg/m^3
Mixing Area	6.67
Blender Area	1.67
Mill Area	6.67
Banbury Mixer Area	13.33
Calender Area	6.67
Plastisol Mixing Room	7.9
Cast Film Line	7.27



TYPICAL CALENDERING OPERATION



FLEXIBLE PVC FILM EXTRUSION WITH IN-PLANT COMPOUNDING



Note: ↑ *indicates potential VCM loss location.*

TYPICAL PVC PIPE EXTRUSION OPERATION

of various resins, fillers and so forth. When the mixture is homogeneous it is either transferred to a deaerator or the mixing vessel may be closed and a vacuum applied to remove entrained air carried in by the solid components. After deaeration the plastisol is ready for fabrication. It may be coated on a release paper, on a metal substrate or on a fabric. These items pass into an oven where the plastisol is fused to yield a plastic film which may be stripped from the release paper or a coated metal sheet or fabric. The plastisol may be poured into metal molds which are subsequently heated. This fuses the plastic for later removal from the mold. To produce foamed plastic, the plastisol may be mechanically frothed or a blowing agent such as an azide can be added. The blowing agent releases gas during the fusion step and the result is a sponge-like plastic.

Plastisol fabrication is likely to be less sophisticated, involve smaller plants and be more labor intensive than conventional PVC fabrication. In such operations, the potential for exposure to PVC dust and vinyl chloride monomer is greater. Dispersion PVC and PVC plastisol additive resins are low in residual monomer content when manufactured and are wholly shipped and used in paper bags after a considerable time lag for analysis and warehousing. Accordingly, vinyl chloride monomer exposure in this type of operation is minimal. The attached table from the NIOSH survey in 1974-1975 could be said to be representative of the VCM exposures

in plastisol operations.[26/]

Exposure to dust may be considerable in these operations due to the small particle size of dispersion and additive PVC resins as well as the small particle size of the fillers and pigments. During the fusion step plastisols also give off plasticizer aerosols which appear as a part of total dust. Because dust control is largely an individual matter for each installation to resolve based on plant configuration and the like, no generalized statement can be made for the industry except to point out that the dust is not wholly PVC.

Organosols are a specialized version of a plastisol. Ketones, esters and hydrocarbons are added to the plastisol to yield a low viscosity liquid composition which is sprayed, roller-coated or brushed onto a substrate. The resulting coated substrate is baked to drive off the diluents and fuse the coating.

Solution coating is a small, specialized area of PVC resin fabrication. PVC resins dissolved in organic solvents and applied to a suitably prepared substrate yield coatings with excellent resistance to water, alkalis, acids and weather. The resins used are copolymers produced by solution polymerization or by special suspension resin processes. These resins must be exceptionally free of electrolytes and insoluble materials. The resin typically is dissolved in a mixture of toluene, methyl ethyl ketone and methyl

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26/

Table 26

Summary of Vinyl Chloride Sampling Data by Job
in Fabrication Plant I

Job	n	$\bar{x}^*$ (ppm)	$\bar{x}$ (ppm)	Range (ppm)
Lab Personnel	4	ND	ND	ND
Plastisol Dipping Personnel	40	0.01	0.01	ND–0.06
Total of Personal Samples	44	<0.01	<0.01	ND–0.06
Composite of All Area Samples	4	ND	ND	ND

* $\bar{x}$ = TWA

isobutyl ketone. Pigments and stabilizer are added and the mixture "ground" in a colloid mill or similar device. The resulting coating is sprayed on the substrate and either oven or air-dried. Each coating is formulated for performance in certain areas and coating formulations are closely guarded by individual formulators.

Formulation of coatings is a small scale operation generally dealing with resins in paper bags and solvents in bulk. There is little or no exposure to residual vinyl chloride monomer from most solution resins since VCM is virtually non-detectable in the resin. Dust exposure from resin and pigments is low because only small volumes are handled. Most formulators have fume control systems for control of solvent vapors and these also remove dusts from the work area. Monitoring for vinyl chloride monomer at coating formulators generally shows non-detectable to 0.05 ppmv.

Solvent cast PVC film is a small fabrication operation which is based on solution coating with solvent recovery. Higher molecular weight resins are often used to achieve higher film strength. A high solids vinyl resin solution is cast on a stainless steel belt. Heat drives off the solvent until a very thin transparent film can be stripped off and dried further on heated rolls. The solvent is collected and reused. More expensive solvents, such as tetrahydrofuran, are often used to reduce solution viscosity. Exposures to dust and vinyl chloride monomer are similar to that of a

coating formulator.

PVC and PVC copolymer dispersions are produced for use in latex form for coating, binder and saturant applications. These latexes fall into two categories. One is a PVC homopolymer or copolymer, high in vinyl chloride content, for industrial use. The second is a copolymer latex containing less than 50% vinyl chloride in the polymer. This type of process forms films drying the latex at ambient temperature.

Latexes are formulated with the additives listed earlier for vinyl resins plus thickeners, surface active agents, colloids, solvents and anti-foamers. Open or semi-open vessels equipped with low speed, low shear agitators are used for formulation. Oils such as plasticizers are often emulsified with water prior to addition to the mix.

Depending on the latex the finished compound may be applied to a substrate by dipping, roller coating or spraying and the coated substrate baked to fuse the resin and drive off the water or it may simply be applied and air dried as a latex paint.

When pigments and fillers are used, dust is a potential problem during the charging of the formula mix. There is, of course, no PVC dust. Residual vinyl chloride monomer in the latex is controlled by the latex producer. Latexes containing 10 ppmw or less RVCM do not emit enough vinyl chloride monomer during formulation or application to cause employee exposures in excess of the OSHA standard "action

level". Latexes containing more than 10 ppmw RVCM are usually processed under controlled conditions where employee exposure is within the prescribed limits.

The PVC resin industry is very large and the versatility of the products is such that all uses and modes of application cannot be covered in this brief overview. Some of these include powder coating, blending resin for polyethylene wire compounds, and rug fiber flame proofing. Health hazards in these applications are negligible.

Conversion of semi-finished PVC plastics to finished products involves drilling, cutting, welding, and heating of the material. Considerable concern has been expressed by many persons that heated PVC will breakdown to its monomer or that enough residual VCM is contained in the product to be emitted during heating or welding. There are a number of studies by NIOSH, EPA and others that conclusively show that this is not the case although there can be evolution of plasticizer fumes, acetic acid, hydrogen chloride and, ultimately, oxides of carbon when PVC is heated. Trace amounts of vinyl chloride have been detected in some cases but only after considerable production of irritating gases which would preclude employee inhalation.

As regards vinyl chloride monitoring devices where there is potential massive exposure to vinyl chloride via leaks, vessel rupture or emergency discharge, the most effective monitors are those automatic systems based on organic

vapor detection, chromatographic analysis, and infrared absorption spectroscopy. These give prompt warning of such VCM emissions and permit prompt protective action by the employee. Portable units such as the HNu unit or the Century Systems Corp. OVA-98 are extremely useful for leak control and on the spot monitoring.

Respirators in use for vinyl chloride protection are those prescribed by NIOSH. Most vinyl chloride and polyvinyl chloride producers rely heavily on self-contained breathing air units or hose-fed breathing air masks.

(10) Types of Occupations, Job Classifications, and Industries Where Where Exposure to Either VC or PVC At Any Level May Occur, and The Numbers of Employees Involved in Each Vinyl Chloride and Polyvinyl Chloride Exposure Situation, Separated By Sex and Race

As to the types of occupations, jobs and industries presenting a potential for exposure to either vinyl chloride or polyvinyl chloride, SPI is unaware of any change in these areas whatsoever since the time of the initial OSHA rule making on vinyl chloride. As the industry trade association, SPI neither has nor collects data on the numbers of employees involved in each exposure situation, separated by sex and race.

(11) Appropriate Engineering Controls, Work Practices, and Personal Protective Equipment Available to Reduce Levels of Exposure to VC or PVC Below the Current Standards Or To the Lowest Levels Feasible

The Society is informed that the individual company members of the PVC Safety Group are presently engaging in the use of appropriate engineering controls, work practices and personal protective equipment to reduce levels of exposure to vinyl chloride and polyvinyl chloride to the currently permitted limits.

As to vinyl chloride, the current standard for controlling occupational exposure to VCM is sufficiently stringent that great difficulty has been encountered by industry in coming into compliance with the standard that is currently in effect. Because of its stringency, not all work places are at all times in compliance with the current standard. In short, there are no feasible, additional engineering controls, work practices and/or personal protective equipment available to reduce levels of vinyl chloride exposure below the present level. Therefore, it would seem that the current standard is the lowest level attainable and that techniques to reduce the current exposure levels are not known.

As to PVC, we know of no reason to control exposure to the polymer because polyvinyl chloride is not known to us to be any kind of health hazard.

As to respirable dust which may be associated with certain operations involving PVC production, these dusts are currently regulated by OSHA. Controls are utilized to comply with these regulations viewed by OSHA as adequate to protect workers from any hazard which would be associated with exposure to the dust. Consequently, extensive investigation into appropriate engineering controls, work practices and personal protective equipment available to reduce the levels of exposure to PVC dust further are not areas known to us to have been investigated in any great detail.

As a final comment, it should be noted that inasmuch as PVC dust has not been shown to be a health hazard at levels below those to which it is currently controlled (or at any other level, for that matter) we know of no purpose which would be served by speculating on methods to reduce levels of exposure.

III.

OTHER INFORMATION WHICH INDUSTRY

BELIEVES TO BE OF INTEREST TO OSHA

In addition to the subject matter covered in the Request for Information, the tenor of the Agency's remarks in its Federal Register Notice and the nature of some of the discussions and papers given at the Bethesda Symposium leads SPI to believe that OSHA is misinterpreting and/or misunderstanding some information available to it. Accordingly, the PVC Safety Group is of the opinion that the Agency would be interested in the industry's comments on some reports in which OSHA has shown interest but which do not seem to fit any of the categories of inquiry set out in the Notice. The remarks which follow, then, are addressed to the following studies or reports: Suzuki, Groth, Radike, Maltoni (sputum cytology), Tamburro, Arnaud and Heir.

Groth, "The Role of Aging on Cancer Induced by Vinyl Chloride Monomer" (pp 67-77)

Report of a study of 473 male and 478 female Sprague-Dawley rats to a mean VCM concentration of 948 ppm for 7 hours per day, 5 days per week for a mean duration of 24.5 weeks. Rat ages were 6, 17, 32 and 52 weeks to determine if age at onset of exposure affected the exposed animal.

The most frequently occurring tumor types in both sexes were liver angiosarcoma, pituitary adenomas and mammary tumors. The time of first diagnosis of angiosarcoma was shortest in the oldest age animals. Older rats are more susceptible to angiosarcoma than young adult rats, and female rats are more susceptible than male rats.

~~Since Groth asked for studies designed to test the theory in humans, this report is simply another animal study which flags a need for concern.~~ which concludes that

Radike, "Carcinogenic Effects of Exposure to Vinyl Chloride Monomer and Ethyl Alcohol on Rats: (pp 78-87)

A report of a study of 320 Sprague-Dawley rats, two control groups and two exposed groups. One group of 80 rats had a normal diet and breathed filtered air. The second group of 80 rats had a 5% ethyl alcohol in water diet and breathed filtered air. The third group had a normal diet and was exposed to 600 ppm VCM. The fourth group had a 5% alcohol in water diet and was exposed to 600 ppm VCM. All had Purina Rat Chow as food. Exposure period was 4 hours per day, 5 days per week for 1 year.

Since some animals had more than one tumor, the rates were 82 malignant and 25 benign tumors in 80 rats exposed to VCM; 125 malignant and 26 begnign tumors in 80 rats exposed to VCM and ethanol; 91 malignant and 51 begnign tumors in 79 rats exposed only to ethanol; and 5 malignant and 11 begnign tumors in 80 rats in the control group.

Of real interest is the high rate of tumors in the "alcohol only" group, a rate almost the same as those rats exposed to vinyl chloride but no alcohol, 1.15 for alcohol only to 1.34 for VCM only, although the sites are different.

Maltoni, "Results of Sputum Cytology Among Workers Exposed to VCM and PVC" (pp 120-127)

A report of a study of 6,780 Italian VCM/PVC workers, 4 smears per worker. Controls were from other industries. On classes 2 to 3, near 3, 3 and 4 findings were: 9.4 in plastics industry, 1.5 in plastic materials manufacture, 1.4 in pharmaceutical, 2.8 in metal workers, 0.9 in mining and milling, and 13.1 in chromium industry. In heavy smokers (20 cigarettes per day for as long as 55 plus years), 60,000 sputum smears showed a rate of 0.6.

Tamburro, "Liver Screening Tests for VC Exposed Workers" (pp 230-243)

A report of about 1200 workers studied by a battery of tests at the University of Louisville since 1974. The report is essentially an evaluation of test procedures and has import only insofar as medical evaluations are concerned. Tests with high specificity, such as alkaline phosphatase, do not show as abnormal until advanced disease occurs. Gammaglutamyl transpeptidase had the most positive predictive value, the highest sensitivity and the highest specificity. Indocyane Green (ICG) clearance, on the other hand, shows progressive changes and can be used to determine developing disease.

Critique of Paper No. 22

Arnaud, "Pneumoconiosis Induced by PVC Dust"
(page 303-310)

This is a report of a single case study of a 50 year old man who, in 1974, was studied for PVC pneumoconiosis. He worked as a bagger in a ~~poly~~ PVC plant from November 1945 to December, 1968.

An X-ray in 1968 showed micronodular shadows, and he had a history of chronic bronchitis, apparently from his smoking habits. He left the bagging job and was a shipper when examined in 1974.

A lung biopsy showed granules 0.3 to 0.4 micrometers in diameter, connected by PVC bridges. The particles showed no evidence of degradation.

This report is of little significance because it is a single case and no exposure data are available. It is of interest only because of the presence of PVC and PVC bridges so long after exposure. A study of about 200 other workers in the ~~poly~~ plant, 60 of whom "had been strongly exposed to PVC," showed no x-ray abnormality which could be related to the reported case.

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HEHIR, ~~A~~ CANCER INDUCTION FOLLOWING SINGLE AND MULTIPLE EXPOSURES TO A CONSTANT AMOUNT OF VINYL CHLORIDE MONOMER." (Tr. pp. 87-101)

~~Symposium Paper No. 5~~

This critique ~~was~~ has been prepared not only on the basis of Dr. Hehir's symposium presentation, but also with the aid of a prepublication draft report of the same study[1/]. The latter reveals some fairly significant technical deficiences in the conduct of the study which were not discussed or even acknowledged at the symposium. For example, consider Table 1 of the prepublication draft wherein it is noted that the following numbers of ICR mice were used in the single exposure study:

VCM Dose Level, ppm	Males	Females
0 (control)	82	88
50	90	90
500	90	90
5000	90	90
50000	90	90

Now, turning to Table IV of the same draft, somewhat smaller numbers of animals per group are noted, as follows:

VCM Dose Level, ppm	Males	Females
0 (control)	62	77
50	81	80
500	72	75
5000	68	76
50000	74	82

1/ Hehir, R. M., Bierbower, G., Willigan, D. A., Kolaja, G., Marrs, G. E., Jr., Hinton, D. E., Dimmick, R. L. and Wiles, J. S. Toxicology, Carcinogenicity, and Reproductive Effects of Single and Multiple Exposures to Vinyl Chloride in Rats and Mice. CPSC Pre-Publication Release, April 1, 1979.

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Nonetheless, a footnote to Table IV ~~informs~~ states that the, "(T)otal includes animals from scheduled sacrificed (8 and 18-month periods) and spontaneous deaths." For some unexplained reason, ~~Even worse,~~ however, the group sizes shrink further when one looks at the numbers of animals undergoing histopathological evaluation of the lung (again, from Table IV of the prepublication draft):

VCM Dose Level, ppm	Males	Females
0 (control)	50	70
50	71	68
500	66	73
5000	65	78
50000	61	76

The following is a compilation of the foregoing three sets of numbers and is an expression of the group numbers as precentages of the original group size as shown in the draft Table I.

VCM Dose Level, ppm	Original No. Animals/Group (Table I)		No. Animals/ Group (Table IV) --As Percentage of Original Group Size--		No. Lungs Evaluated by Histopath (Table IV)	
	M	F	M	F	M	F
0 (control)	82	83	70	87	61	80
50	90	90	90	89	79	76
500	90	90	80	83	73	81
5000	90	90	76	84	72	87
50000	90	90	82	91	68	84

One final tabulation, following, shows ~~indicates that for some unexplained reason the lungs from only a portion of~~ the percentage of animals available were examined histopathologically (data from draft Table (V): for examination whose

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VCM Dose Level, ppm	No. Animals/ Group		Lungs Evaluated No.		(Percentage) %	
	M	F	M	F	M	F
0 (control)	62	77	50	70	81	91
50	81	80	71	68	88	85
500	72	75	66	73	92	97
5000	76	82	65	78	86	95
50000	74	82	61	76	82	93

These tissue losses, in the case of the lung, ~~are~~ were not accounted for in either the symposium presentation or the prepublication draft. It is submitted that this demonstrated loss of lung tissue is unacceptable in an inhalation study, and in this particular case, when the lung is ~~indicated~~ suggested as the target organ for ~~carcinogenicity~~ tumorgenicity, such losses are even more unacceptable.

It is not our intention to provide an exhaustive analysis of data and technical deficiencies of the study. Suffice it to say, however, that in this day and age of stringent good laboratory practice regulations, it might behoove Hehir et al. to assure themselves that their study is indeed of the quality implied in the symposium presentation, and that all the data do support the conclusions they reached.

Turning now to the biological aspects of the study, since the findings in the rat portion of the the study were negative, the main thrust of the following comments will be directed at the mouse studies.

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A. Single Exposure Study (ICR Mouse)

Hehir reported the following salient findings in this study:

VCM Dose Level, ppm (One Hour Exposure)	Incidence of Pneumonitis	(As % of Animals Examined Histopathologically) Pulmonary Adenoma	Pulmonary Carcinoma
		MALES	
0 (control)	2	8	0
50	6	11	0
500	29	12	0
5000	25	22	2
50000	34	51	2
		FEMALES	
0 (control)	9	11	0
50	10	9	0
500	21	14	1
5000	22	13	0
50000	13	18	3

Perusal of these data reveal a rough parallelism between the incidence of pneumonitis and the incidence of pulmonary adenomas for both sexes, but particularly for the males. Indeed, it could be suggested on the basis of these data, as well as on the basis of the mortality and growth curves (prepublication draft Figures I and II, and X and XI, respectively) for the males and females, that these tumor incidence data should not be combined. Examination of the data for the females, then, suggests no real difference between the controls and any treatment group for that sex.

Examining the data for the males only suggests a significant correlation between the incidence of pneumonitis and the incidence of pulmonary tumors. However, it is difficult to attribute the pneumonitis at sacrifice to VCM exposure occurring months earlier. It is most likely that any VCM-induced pneumotic-like lesion would have either resolved within a relatively short period after the exposure, or would have fibrosed and ~~would~~ appeared as a typical fibrotic lung lesion.

Review of the growth data for the ICR male mice (prepublication draft Figure X) reveals a marked drop in body weight in all groups starting at about week 28 and persisting until about weeks 40-45. Of all the groups, only the control group returned to near normal weight, although this did not occur until about week 65. Also, immediately following the period of weight loss there was a steep ascendancy in the spontaneous mortality curves. Thus, it is apparent that some extraneous factor, quite possibly an infectious pneumonitis, afflicted the colony.

With further regard to the period of weight loss mentioned above, as well as the nearly complete recovery by the unexposed control group, the influence of diet on spontaneous tumor incidence has long been recognized (see, for example, Magee, P. N., Tests for Carcinogenic Potential, in Methods in Toxicology, G. E. Paget, Ed., Philadelphia, F. A. Davis Company, 1970).

One final point with regard to the single exposure study: The CPSC investigators should be aware of the early report of Steiner and Loosli[2/] in which it is stated that "The infection produced great tumor-like epithelial

2/ Steiner, P. E. and Loosli, C. G.
The Effect of Human Influenza Virus (Type A) on the Incidence of Lung Tumors in Mice.
Cancer Res. 10:385 (1950).

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CHAMBER CONTROLS

hyperplasia during the recovery stage. Some Influenze-induced lung lesions persisted throughout the life of the animals." (Emphasis added)

It is our view that this portion of the CPSC study must be more fully and critically evaluated, and that Hehir and his co-workers must at least address the issues raised in this commentary.

B. Multiple Exposures (A/J Mice)

It is apparent from Tables VII and VIII of the prepublication draft that the A/J strain of mouse has a high spontaneous incidence of pulmonary adenomas, as shown below:

Incidence of Pulmonary Adenomas
In A/J Control Mice
(As Percentage)

Study	Male	Female
10 x 500 ppm	35	34
100 x 50 ppm	25	40

Saddler Ph.D.

~~Numerous workers in the area of chemical carcinogenesis have cautioned against selecting strain/species with a high spontaneous tumor incidence for carcinogenesis bioassays[3]. For this reason alone the results of this portion of the study are questionable. In addition, good experimental design in a study such as this would dictate equal or near equal size control group and treatment groups[4]. The ratio of treated to control animals in the case at hand is approximately 2:1 in each instance. Hehir et al do not refer to the statistical methods used in analyzing the data when they discuss significance, and such a description is necessary to determine if their conclusions are indeed appropriate.~~

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CONTINUE WITH P 7 AT C.

~~3/ References to be supplied~~

3/ "THE TESTING OF CHEMICALS FOR CARCINOGENICITY, MUTAGENICITY, AND TERATOGENICITY," MINISTER OF HEALTH AND WELFARE, CANADA, 1973

4/ "PRINCIPLES AND PROCEDURES FOR EVALUATING THE TOXICITY OF HOUSEHOLD SUBSTANCES," WASHINGTON, D.C., NATIONAL ACADEMY OF SCIENCES, 19

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"A review of historical control data for this strain should reveal if the above incidences are greater than normally expected. If so, it would suggest some extraneous factor had impacted on the experimental animals, control and treated. If, on the other hand, the incidence of pulmonary tumors in the control mice in this study is within the expected range of normal, the strain ~~is~~ was probably a poor choice for evaluating lung tumorigenesis. In general, species/strains with a high incidence of spontaneous tumors should be avoided in carcinogenesis bioassays[3]. It would also have been useful had the experimental design included control groups equal in numbers to the treatment groups. Such design is dictated by ~~current~~/good toxicological practice[4].

"Another facet of Hehir's experimental design which is not apparent is whether or not the control animals were handled in the same manner as the exposed animals, especially whether or not they were sham exposed. In view of the number of extraneous factors which are known to affect spontaneous tumor incidence in experimental animals[5], control and treatment groups should be as nearly equivalent as possible in all regards except exposure to the test agent.

ADD ¶ FROM BOTTOM P 6 - MARKED STET

3] } FROM BOTTOM, P 6
4]

5/ Bickerton, R. K.
Spontaneous Tumors and Related Changes. In "Carcinogenesis Testing of Chemicals," L. Golberg, Ed., Cleveland, CRC Press, 1974.

As a final note to this section, and in part because the reservations expressed above, it is suggested that a direct comparison of results of the study with ICR mice on the one hand, and A/J mice on the other, may well be inappropriate.

C. General Comments

"There are ~~two~~ other aspects of the study as a whole which are troublesome. Firstly, the ~~apparent primary target~~ ~~for tumorigenesis~~ organ/tissue in these mice ~~is not~~ responding to the supposed carcinogenic doses of VCM was the lung ~~the vascular epithelium, i.e., the characteristic by the angiosarcoma, but rather is the lung.~~ Secondly, if the mouse is susceptible to the doses employed in the study, at least some microscopically detectable changes in the rat would be expected, the reported eosinophilic foci in the liver ~~cell alterations~~ notwithstanding. In our view, these two facts make the findings in the mouse lung even more suspect.

"In summarizing, it should be pointed out that the CPSC study as it is now reported contributes little to the understanding of VCM carcinogenesis. This is truly unfortunate in view of the fact that over 3000 animals were employed (and considerable resource expended). However, we do not suggest that nothing can be concluded from the study, but, rather, that any conclusions must await a comprehensive evaluation of the data developed. We would hope the authors would undertake such an evaluation before final publication of the work.

"As a final note, we would like to point out to OSHA that information and data relevant to the CPSC study has been requested from both the Commission ~~[4]~~ and the performing laboratory [6] [7]; the requests have fallen on deaf ears. We find this an unfortunate situation ~~which forces consideration of proceeding under~~

~~[4] Purchase Letter~~

~~[5] Torkleson Letter~~

[6] Letter dated August 20, 1979 from ICI, Ltd. to Dr. J. McLaughlin, Jr. of CPSC and Dr. B. McNamara of Edgewood Arsenal.

[7] Letter dated _____ from Dow Chemical, U.S.A. to _____

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~~f8.~~ In addition, consideration must be given to requesting a full audit of the study, ~~if it is to be used in regulatory decision/making.~~

V. L. Kirkland
April 29, 1980
8-Page Draft

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fresh letter

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IV.

CONCLUSION

(To be written.)

Still!

(1) Chairman Schaefer opened the meeting by reporting that the Steering Committee had appointed a Nominating Committee to fill the three terms of membership on the Steering Committee which expires May 31, 1980. He also noted that the committee would be nominating a slate of candidates for officers of the Group. The Nominating Committee is Messrs. Todd Walker, Chairman, Don Spencer and Dr. Ross Adams. The slate of candidates will be submitted to Mr. Lawrence for letter ballott.

(2) Dr. Adams, Vice Chairman, chaired the remainder of the meeting.

(3) Dr. Torkelson distributed a report on the activities of the Health Committee. Regarding the computerized bibliography, Dr. Adams reported that the Steering Committee recommended that $18,000 be authorized for this project. The recommendation was unanimously approved.

The group commended Dr. Torkelson and Mr. Thomas for their efforts in providing U.S. and European scientific attendance at the OSHA symposium. Several Companies indicated they would be making individual submissions to OSHA in response to their request for information on VCM and PVC. Mr. Hadley requested that they also send him copies of their submissions.

(4) Mr. Hadley distributed a "draft" substance of submission to the EPA Cancer Policy Rulemaking Record on cost of compliance to OSHA and EPA regulations (copy attached). He explained that once the submission was approved, the individual company data supplied to him would be destroyed. Mr. Hadley distributed a 2 year tabulation of discharge data.

Messrs. Laundrie and Baise reported on the two meetings held with EDF noting that a written report was included in Mr. Hadley's letter of April 25, 1980. Mr. Baise also noted that the EDF position was to ultimately eliminate VCM emissions. He urged members to watch the EPA action on benzene emissions from maleic anhydride plants as a precedent setting activity. Mr. Laundrie reported that no more meetings were scheduled with EDF.

After additional discussion, it was moved, seconded and carried that a committee be established to develop alternative approaches in the public and political arenas as well as the agency arena which will substantiate the responsible actions thus far taken by industry to elucidate the cost-risk-benefit considerations of future regulations. Dr. DiLiddo was appointed Chairman of the Committee.

(5) Mr. Hadley reported that the Lawyers Committee recommended not to get involved in the Tenneco/Hooker petitions.

(6) Mr. Downey reported that there was little media interest in the OSHA symposium. He also reported that two PVC/VCM Management Summaries were being prepared on the symposium; one a summary, the other a critique of the proceedings. He also said that a backgrounder on PVC dust would be prepared and the PVC Q&A booklet would be updated. Lastly, he reported that the PR Committee is running $2,000/month below budget.

(7) Mr. Hadley reported the first draft of comments in response to the OSHA request for information was mailed on April 25 and 25. He noted that the Health Committee would be meeting May 1 to develop a second draft and May 8 and 9 to finalize comments. He further noted that subsequently he did not foresee any problem in submitting developed comments after the close of the official response date.

(8) Mr. Walker gave the Financial report (copy attached). Dr. Adams reported that the Steering Committee recommends that the Group raise $250,000 for the upcoming year, 50% to be assessed now and 50% to be assessed in six months. The recommendation was carried unanimously.

(9) Mr. Hadley reported that EPA was due to issue rules on hazardous waste and that EPA had recently prohibited the manufacture of 6 new phthalate esters under Section 5 of TSCA. He also reported that the Steering Committee declined an invitation by the Chlorine Institute to join their suit on the chlorine standard.

(10) There being no further business, the meeting adjourned at 11:45 A.M. No date was set for the next meeting.

Respectfully submitted,

H. P. Toner
Asst. Technical Director

May 14, 1980

SUBSTANCE OF SUBMISSION TO EPA

CANCER POLICY RULE MAKING RECORD

The Environmental Protection Agency has repeatedly cited figures concerning the costs incurred by the vinyl chloride and polyvinyl chloride industries for in coming into compliance with its regulation of vinyl chloride emissions under §112 of the Clean Air Act. To ensure that the Agency is using proper figures and in order that the actual figures could be evaluated by the industry, the following data were developed by SPI's Polyvinyl Chloride Safety Group.

1. Cost of Capital Equipment Investments Required to Conform With OSHA and EPA Vinyl Chloride Standards from 1974 to Present - in millions of dollars.

OSHA		EPA		TOTAL	
VC	PVC	VC	PVC	VC	PVC
$19.8	158.	79.4	119.	99.2	277.

2. Yearly Operating Expenses Required to Comply With OSHA and EPA Vinyl CHloride Standards from 1974 to Present - in millions of dollars.

	OSHA		EPA		TOTAL	
	VC	PVC	VC	PVC	VC	PVC
1974	$0.6	3.7	0.8	3.4	1.4	7
1975	.9	4.8	1.4	4.1	2.3	8.9
1976	1.5	6.1	1.9	4.3	3.4	10.4
1977	2.2	7.6	2.6	5.3	4.8	12.9
1978	2.2	8.5	6.1	9.7	8.3	18.3
1979	2.8	11.9	10.4	19.5	13.2	31.5

In the process of developing these statistics, SPI also collected capacity-related information. In so doing, The Society was able to quantify the loss of capacity attributable to the two regulations. Comparing nameplate capacity and practical operating capacity, it has been determined that the vinyl chloride producing industry can operate to only 93% of capacity and that the PVC industry can only operate to 89% of nameplate capacity. This reduction in capacity is due to process modifications required in order for the industry to obtain compliance with the OSHA and EPA regulations applicable to vinyl chloride.

This survey was conducted by mailing a copy of a survey form to each company for the preparation of a response. After the response was prepared a representative of The Society contacted each member company to gather the data. Based on the results obtained it can be stated that the foregoing data are based on responses from more than 80% of the entire vinyl chloride producing industry and over 60% of the entire polyvinyl chloride producing industry.

Should the Agency have any questions or comments regarding the foregoing, cohtact should be established with Mr. John R. Lawrence, Technical Director of SPI, at:

Mr. John R. Lawrence
The Society of the Plastics
Industry, Inc.
355 Lexington Avenue
New York, New York 10017

(212)573-9400

SPI-PVC SAFETY GROUP
SOURCE AND DISPOSITION OF FUNDS
AS OF 2/29/80

				AMOUNT
SOURCE:				
1. Carryover from 1978/79 Operations-Per Ledger Printout			$24,931.53	
Less: Hill and Knowlton Billing for May Services Not Included in Public Relations Expense as of 5-31-79.			(5,203.74)	
Net Carryover From 1978-1979				$ 19,727.79
2. Assessments:	Total Assessments	Assmts.Paid thru 2/29/80	Net Assmts. Due at 2/29/80	
1978/79 Assessment Unpaid at 5/31/79	$ 18,840.00	$ 18,840.00	$ -	
1979/80 Assessments-#1	103,843.00	103,843.00	-	
-#2	200,000.00	-	200,000.00	
Total Assessment Income		$122,683.00		122,683.00
Net Assessments Receivable (See Attached Detail)			$200,000.00	200,000.00
3. Meeting Income:				-
4. Sales of Literature:				145.00
Total Funds Available - 2/29/80				$342,555.79
DISPOSITION:				
1. Current Year Expense:				
Legal Expense - Actual thru Jan., 1980		$137,032.23		
- Febr.,1980 Accrual		16,574.57	$153,606.80	
Public Relations Expense-Actual thru Dec., 1979		$ 25,239.30		
- Jan. & Febr., 1980 Accrual		8,611.64	33,850.94	
Meeting & Travel Expense			1,705.65	
Research & Development Expense			1,300.00	
Office Supplies & Expense			133.24	
Telephone Expense			546.70	
Total Expenses				$191,143.30
Net Funds Available at 2/29/80				$151,412.46

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SPI-PVC SAFETY GROUP
ASSESSMENT INCOME ANALYSIS
1979-80 ASSESSMENTS

COMPANY	Total 1979-1980 Assessments	Payments Received thru 2-29-80	Net Assmts. Receivable at 2-29-80
Air Products & Chemicals	$ 6,880	$ 1,920	$ 4,960
B.F. Goodrich Chemical	49,130	16,530	32,600
Borden Chemical	16,940	3,840	13,100
Conoco Chemicals	26,463	9,223	17,240
Diamond Shamrock	35,040	12,300	22,740
Dow Chemical	43,550	15,150	28,400
Ethyl Corporation	10,530	3,770	6,760
Firestone Plastics Co.	11,620	3,080	8,540
General Tire & Rubber	2,370	850	1,520
Goodyear Tire & Rubber	3,320	1,880	1,440
Great American Chemical	1,500	540	960
Hooker Chemical	3,770	1,350	2,420
ICI Americas	6,450	2,310	4,140
Pantasote Co. of N.Y.	2,900	1,040	1,860
PPG Industries	8,600	3,080	5,520
Shell Chemical Co.	33,060	11,840	21,220
Shintech, Inc.	7,080	2,540	4,540
Stauffer Chemicals	11,800	4,420	7,380
Tenneco, Inc.	16,110	5,770	10,340
Union Carbide	3,770	1,350	2,420
Uniroyal Chemical	2,960	1,060	1,900
TOTALS	$303,843	$103,843	$200,000

SPI-PVC SAFETY GROUP
EDC COMMITTEE
SOURCE AND DISPOSITION OF FUNDS
AS OF 2-29-80

				AMOUNT
SOURCE:				
1. Carryover from 1978/79 Operations-Per Ledger Printout				$(8,818.02)
2. Assessments:	Assessment	Assmts.Paid thru 2/29/80	Net Assmts. Due at 2/29/80	
1978/79/80 Assessment	$ 31,000.00			
Less: Paid in 1978/79	6,000.00			
Bal.Due in 1979/80	25,000.00	$ 24,000.00	$ 1,000.00	
*Plus: Assmts. Overpaid		768.00		
Total Assessment Income		$ 24,768.00		24,768.00
*Net Assessments Receivable			1,000.00	1,000.00
*(See Detail Following)				
Total Funds Available-2/29/80				$ 16,949.98
DISPOSITION:				
1. Current Year Expenses:				
Legal Expense - Actual thru Jan., 1980		$ 18,189.53		
- Febr.,1980 Accrual		46.78	$ 18,236.31	
Meeting & Travel Expense			100.63	
Telephone Expense			239.36	
Total Expense				18,576.30
Net Funds Available - 2/29/80				$ (1,626.32)

SPI-PVC SAFETY GROUP
EDC COMMITTEE
ASSESSMENT INCOME ANALYSIS

Company	Total Assmts.	Payments Received 1978-79	Assmts. Due 1979-80	Payments Received 1979-80	Net Assmts. Receivable At 2/29/80
Borden Chemical Corp.	$ 992	$ 1,000	$ (8)	$ -	$ (8)
Continental Chemicals	2,325	-	2,325	1,325	1,000
Diamond-Shamrock Corp.	3,782	1,000	2,782	2,782	-
Dow Chemical	9,672	-	9,672	9,672	-
Ethyl Corporation	1,922	-	1,922	1,922	-
B.F. Goodrich Chemical	2,015	-	2,015	2,015	-
ICI Americas	1,395	-	1,395	1,395	-
PPG Industries, Inc.	2,418	1,000	1,418	1,418	-
Shell Chemical Co.	5,239	1,000	4,239	4,239	-
Stauffer Chemical Co.	620	1,000	(380)	-	(380)
Union Carbide Corp.	620	1,000	(380)	-	(380)
Totals	$31,000	$ 6,000	$25,000	$24,768	$ 232

Overpaid (-)

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