

January 15, 1980

Staff Report

ISSUE REPORT: INDUSTRIAL HEALTH (TOXICITY)

Issue Coordinator : H. F. Tomforhde III
Issue Specialist : T. J. Newcomb
Staff : H. P. Toner

OSHA CARCINOGEN POLICY

SPI counsel attended a pre-publication briefing on the OSHA carcinogenic policy January 9. Without reviewing the document in detail it appears that OSHA has recognized the SPI position that there should be provisions for exemptions of products containing minimal residual monomers and to permit processors to continue normal operations when exposures are lower than action level. Further analysis of the policy will be made on its publication.

TOXICOLOGY COMMITTEE

The Toxicology Committee submitted comments on EPA's proposed revised PMN (pre-manufacture notification) form. In essence, the SPI response was that for most new polymers (thermoplastics) very little of the information requested on the form was necessary to establish a conclusion that the manufacture of the polymer presented no unreasonable risk to health or the environment.

As a result of the "issue meetings" in Dusseldorf, the Committee has prepared a discussion paper questioning the requirements for PMN or polymer registration in the U.S., Europe and Japan.

The draft report on the literature search on the toxicity of polymers has been reviewed with the contractor (Calculon). Several suggestions were made as to how absence of adverse effects even on polymers whose composition was inadequately defined could support a conclusion of very low risk. The second draft is expected imminently.

The Committee has drafted a letter to additive suppliers requesting toxicity data on specific additives. The letter has been approved by Counsel and will be sent out by the end of the month.

SELF FUNDED GROUPS

AN Polymers Group - The AN Group submitted comments on EPA proposed water quality criteria for AN. The major points made were the use of a conservative risk estimate leading to limits in the parts per trillion range, the inability to measure such limits, and the absence of data that such limits could be obtained.

ISSUE REPORT

INDUSTRIAL HEALTH (TOXICITY)

TOXICOLOGY COMMITTEE

The Toxicology Committee continues the development of its position that polymers (thermoplastics) are not in the same category as monomers intermediates and other chemicals. The Committee reviewing the draft report on a literature search on the toxicity of polymers prepared by Calculon. At first glance the results are disappointing in that insufficient literature was uncovered to support (or refute) or "intuitive" argument.

The Committee is also preparing comments on the EPA repropoed form for pre-manufacturing notification (PMN) pointing out that only a few sections apply to polymers, the bulk of the data being requested is not applicable to thermoplastic polymers.

The Committee is also renewing its quest for toxicity data on additives. Based on a discussion with several additive suppliers a "rifleshot" rather than a "shotgun" approach will be tried this time.

SELF FUNDED GROUPS

AN POLYMERS GROUP - The AN Group is preparing comments on EPA proposed water quality criteria for AN in fresh water and salt water. The proposed criteria are based on a calculated risk assessment with risks to human health of 1 in 100,000, 1 in 1,000,000 or 1 in 10,000,000. The criteria levels turn out to be 80, 8 or 0.8 parts per trillion. The Group will be challenging the conservative risk calculation, the trivial nature of the levels and the inability to measure such levels under operating situations.

AD HOC EPICHLOROHYDRIN COMMITTEE - The EPI Committee is preparing a "model standard" for exposure to epi. The Committee is also compiling exposure data for downstream applications such as epoxy flooring a pipe fabrication.

AD HOC PET SAFETY COMMITTEE - The PET Committee has just initiated an in vivo metabolism study of the oligomer extractable bis-hydroxyethyl terephthalate (BHET). The study is expected to confirm that BHET is broken down in the body to terephthalic acid and ethylene glycol, both of which are already under study by other organizations.

VINYL ACETATE TASK FORCE - As previously reported the Task Force is conducting a subchronic toxicity study of VA at Hazleton Laboratories UK. The 90 day feeding and inhalation exposures are complete, pathology is in progress. The Task Force is evaluating additional metabolic and pharmacokinetic studies to confirm the indication from the initial metabolic studies that VA is rapidly converted to acetaldehyde and CO₂. All results of the animal tests to date are "clean".

Toxicity

The Problem:

Toxicity has become an issue in the plastics industry as a result of the increased industry, government and public awareness of the potential for adverse long term effects on health and the environment due to exposure to chemicals. Industry concern has been manifest by increased research on the toxic effects of chemicals. The enormity of the scope and cost of the data gathering effort has spurred the desire to develop cooperative programs within industry. The increased public and government awareness has been manifest in laws such as the Toxic Substances Control Act (TSCA) and specific regulations such as the OSHA and EPA regulations of vinyl chloride.

SPI Response

The SPI has responded to this issue through the Toxicology Committee and the various Polymer/Monomer Safety Groups.

Toxicology Committee

The Toxicology Committee is the "generalist" committee of the PAC in the areas of toxicology and health in the context of occupational and environmental exposure. The Toxicology Committee:

- Reviews and, when appropriate, responds to government proposed generic policies on behalf of the plastics industry.
- Provides stimulus and the means for the collection, review and dissemination of toxicity data on plastics and plastics precursors for industry-wide use; and provides the opportunity for joint testing programs.
- Provides an organizational network through which self funded, specific interest, committees or groups can be organized e.g. PVC Safety Group, ad hoc Epichlorohydrin Committee, Vinyl Acetate Task Force.

Completed and In Progress Activities

General

- Policy statement for SPI Resin Producers.

Regulatory

- Comment on Proposed TSCA Inventory Rules.
- Comment on OSHA Carcinogen Proposal. (Particular emphasis on Clements Categorization).
- Comments on TSCA Sec. 8E Substantial Risk Guidance.
- Comment on TSCA Pre-Manufacturing Notification (PMN). Proposed Requirements.
- Comment on TSCA PMN Testing Guidance.

(over)

- Chemical Toxicity
- Preliminary "Inventory" of chemical substances encountered in the plastics industry.
- Collecting of Toxicity Data (In progress - over 400 "items to date")
- Preliminary Review and Priority Setting.
- Literature search on toxicity of Butene-1 and Hexene-1.
- Compilation of protocols for evaluating Processing Fumes.
- Literature search on the toxicity of polymers (In Planning Stage).
- Subchronic Study of Tetrafluoroethylene (In pre-planning stage).
- Vinyl Acetate Task Force.
- ad hoc Epichlorohydrin committee.

1979-80 Activities

- Develop protocols and data on Processing Dusts & Fumes.
- Obtain Exemption of Polymers from PMN Requirements.
- Codify data collected.

SELF FUNDED - SPECIFIC INTEREST GROUPS

PVC Safety Group

The PVC Safety Group was formed to respond to the situations (regulatory and public) which developed and continue to arise since it was learned that VCM has caused angiosarcoma in workers exposed to high levels. In addition to vigorously commenting on the OSHA, and EPA regulations for vinyl chloride, the group published papers on "PVC and Health" and "What Every Employee Should Know About PVC and What You Should Tell Others".

The Group has formed an EDC (ethylene dichloride) subcommittee to respond to the recent OSHA request for information on EDC. EDC was determined to be carcinogenic to rats and mice in an oral bioassay conducted by NCI.

AN Polymers Group

The AN Polymers Group was formed to respond to OSHA proposal to regulate AN as a carcinogen. AN has caused tumors in laboratory animals and there is a "suggestive" association with lung and colon cancer in heavily exposed workers. The Group effort was successful in obtaining a tough but reasonable standard for occupational exposure - 2ppm TWA₈.

REPORT ON THE SPI TOXICOLOGY PROGRAM
PRESENTED BY H. P. TONER
TOXICOLOGY FORUM, ASPEN, COLORADO, JULY 25, 1978

Several years ago the Public Affairs Committee of the SPI identified toxicity as another of the issues with which the plastics industry was faced. This was along with issues such as combustibility, solid waste and energy, which were then being addressed. The SPI toxicology committee is the force which has evolved from this initial awareness. While major programs have been undertaken by groups of interested companies in response to regulatory activities affecting specific materials such as PVC and acrylonitrile based polymers the Toxicology Committee is addressing itself to the broad interests of the plastics industry.

The charter of the Toxicology Committee is:

- 1) To recommend policies for SPI and its members that serve as guidelines for responsible action in the field of toxicology and related industrial health affairs;
- 2) To review government policies and regulations and make recommendations for such SPI response that it believes is necessary to properly protect and promote the legitimate interests of the plastics industry;
- 3) To represent SPI in its relations with the government, other trade associations, national and international, and the public;
- 4) To coordinate the collection, review and dissemination of toxicological data on materials of interest to the plastics industry and to provide the means for joint development of data where it considers data to be insufficient.

The Toxicology Committee has taken several important steps. The initial step was the adoption of a policy statement for resin manufacturers which reads in part as follows:

"Products made of plastics are important contributors to the quality of life in our society. The prospect that certain materials used to make plastics may have toxic effects on human health or the environment is a matter of concern of the plastics industry, its employees, and the general public. The SPI recommends to its member companies that they not only conduct their operations in accordance with existing laws and regulations but also utilize to the best of their ability, other safety procedures based on best available current scientific knowledge."

The Engineering Plastics Subcommittee is in the initial talking stage regarding a subchronic study of tetrafluoroethylene.

Lastly, the Vinyls Subcommittee identified vinyl acetate as a major chemical for which the toxicological data base should be expanded. The vinyl acetate task force has outlined a two phase program of testing. Phase one covers a range finding study preliminary to a three month oral and inhalation study, a teratology study and a metabolism study. The task force is attempting to make this study an internationally sponsored project. We have had several promising discussions with the European producers through APME - the Association of Plastics Manufacturers of Europe. The Japanese producers have been a little bit inscrutable but contacts are continuing and we are hopeful of their support. We would hope to begin the study in the fall of this year.

That is a capsule summary of the status of the SPI Toxicology Program. In our slightly more than one and a half year life we have a smorgasbord of activities representing the diversity of the industry itself.

We appreciate this opportunity to report on our program and welcome your comments and inputs.

Thank you.

The other is concerned with

- Polysilicones
- Phenolics
- Epoxy
- Urea Polymers
- Melamines
- and other thermosetting resins

The Styrenics Subcommittee covers

- Polystyrenes
- ABS polymers
- SAN polymers
- and styrene butadiene polymers

And lastly the Engineering Plastics Subcommittee which covers

- Nylons
- Acetals
- Polycarbonates
- Thermoplastic Polyesters
- Acrylics
- AN Copolymers
- Fluoropolymers
- Polyimides
- Polyphenylene Oxides and sulfides
- and Polysulfones

The polymer types just mentioned should give you an idea of the scope of our endeavor.

All the subcommittees have made a preliminary identification of the chemicals encountered in their area. The preliminary screen includes more than 400 chemicals in the category of raw materials, intermediates and finished products and over 500 chemicals used as additives.

The collection and sharing of information is now an ongoing process. To conduct the process in a somewhat orderly manner the subcommittees identified materials on a priority based on commonality of interest. The information collected to date varies from Material Safety Data Sheets, literature searches, toxline searches, and summaries and bibliographies, to toxicity test reports including acute studies, metabolism studies, several subchronic studies and two chronic studies.

Three of the subcommittees, Polyolefins, Vinyls, and Engineering Plastics, are undertaking the formidable task of collecting and reviewing data on selected additives. Data has been received on about half of the first 60 additives selected because of common interests.

The Vinyls and Polyolefins Subcommittees are also collecting information on dusts generated from their respective polymers.

The Engineering Plastics subcommittee is wrestling with the problem of determining decomposition fumes during polymer processing and fabrication.

As far as individual chemicals are concerned - the Polyolefins subcommittee has achieved the ultimate in committee work - raised funds - and have contracted for a literature search on butene-1 and hexene-1.

On the Regulatory front the committee has been a watchdog over activities of EPA-TSCA, OSHA and CPSC. SPI already had existing groups interacting with FDA on plastics packaging.

As with all industry, TSCA has taken quite a bit of attention. First it was the inventory reporting requirements, then substantial risk guidelines and now pre-manufacturing notification. The OSHA Carcinogen Policy also drew considerable attention. In addition to reviewing and supporting the AIHC alternatives SPI developed its own testimony supporting the concepts of product exemptions and the action level exemption. These exemptions are critical for a large segment of SPI's constituency, - the plastics processor. The processor characteristically has minimal - to - no employee exposure and very limited administrative resources with which to deal with government regulations.

SPI spoke at the EPA public meeting on their carcinogen policy, and we are now reviewing the CPSC policy.

In addition to these activities at the general policy level the Toxicology Committee has established several subcommittees which are grouped by generic polymer family. The purpose of these subcommittees is to:

- 1) Identify the raw materials, additives, intermediates, finished products, by products, decomposition and degradation products and waste products of their respective plastics - a mini TSCA if you will;
- 2) Collect, share and evaluate the available toxicological data on those materials;
- 3) Make judgements as to the priority to be given to the development of additional toxicological data and;
- 4) Provide the framework for cooperative studies on particular materials.

The Generic Polymer Subcommittees are:

Polyolefins - including

High and Low Density Polyethylene
Polypropylene
Polybutene

The Vinyls Subcommittee covering

Polyvinyl Alcohols, Acetates, Butyrals and Formal and of course the Polyvinyl Chloride Resins

The Thermosetting resins are split in two subcommittees. One covers

Polyurethanes
Isocyanates
Polybutadienes
Unsaturated Polyesters
Alkyds

JANUARY 29, 1980

R. D. MULLINEAUX

Dick

Per our telcon, here is the letter from Tomfohrde. I've asked J. Hamil to coordinate this for you and he can give you further background into what the committee responsibilities are. As I mentioned, I would like to recommend someone because I think this is an important effort. John will prepare the formal nomination if we agree on one. Hopefully this can be done by February 15, 1980.

Thanks much for your help.

Attachment

cc - J. Hamil


E.F. McMAHON

CHIEF OF POLICE	
JAN 30 1980	
RMJ	_____
RMJ	_____
JJM	_____
WGD	_____
STV	_____

Administrative	_____
Investigative	_____
Legal	_____
Public Affairs	_____
Training	_____
Records	_____