



6-352-L
MINUTES

RECEIVED

JUN 06 1978

Date June 1, 1978

INTEROFFICE
MEMORANDUM

Subject June TSCA Committee Meeting
LAW DEPT.

To TSCA Compliance Committee

(Location, Organization, or Department)

From C. E. Blades

(Location, Organization, or Department)

Distribution: W. M. Smith W. Ent
L. B. Tepper G. Handley
R. H. Schenck W. Custead
A. J. Diglio G. Frieling
J. C. Novak M. G. Zellner
J. H. Body C. D. Kalb
J. Egan J. Urenovitch
R. Mayo E. I. Handwerk

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The next meeting of the TSCA Compliance Committee is set for MONDAY,
JUNE 12, 1978, at 1:30 PM in the Main Office Building, Allentown, ROOM 113G

The objective of the meeting will be met when assigned tasks have been completed and the current issues have been identified with appropriate assignments made to assure continuing ability of the company to comply with developing regulations under TSCA.

The Agenda is:

- (1) Approval of minutes of May 1, 1978 meeting.
- (2) Follow-up business
 - (i) R. H. Schenck assignment for draft to go on purchase orders.
 - (ii) Inventory report - document file status.
 - (iii) Trademark inventory update (status, issues, new input).
 - (iv) New product introductions prior to end of year.
 - (v) MID progress report.
 - (vi) PCB bulletin. Are there any questions?
- (3) Substantial Risk Notification - Procedure questions
- Distribution of procedure.
- (4) New developments within EPA (PMN, Tiers, etc.)
- (5) Forecast of EPA actions for upcoming year. Issues.
- (6) Ancillary activities -- RCRA - Waste Disposal
OSHA - Carcinogen Policy
EPA - Spills into Waterways

CEB:sk

C. E. Blades

(320)

AP00049023

RECEIVED

6-35211
Date May 1, 1978

INTEROFFICE
MEMORANDUM

MAY 12 1978
Subject
LAW DEPT.

TSCA Meeting Minutes - May 1, 1978

To Distribution

From C. E. Blades

(Location, Organization, or Department)

Piscataway

(Location, Organization, or Department)

Distribution: R. Fleming W. L. Ent
D. Baker J. Urenovitch
W. M. Smith J. M. Egan
L. B. Tepper T. B. Collins
J. C. Novak M. G. Zellner
A. J. Diglio A. I. Dalton
R. H. Schenck W. Custead
J. H. Body G. Frieling
E. I. Handwerk R. Mayo
G. G. Handley

1. Approval of Minutes - TSCA Meeting/March 13, 1978

Minutes approved with the following comments: .

- a) R. H. Schenck to prepare a statement of warranty on purchase agreements for vendor certification that supplied products have been reported for the inventory.
- b) The Ames mutagenicity test result on 2-ethylhexaldehyde was negative.
- c) NF₃ has been submitted for Ames testing. Results still pending.

✓ 2. Inventory Reporting

- a) At the time of this meeting, inventory reporting forms for CSD, IGD, and Houdry Chemicals had been submitted to the EPA. Reports for Industrial Chemicals and MSD will be certified and mailed today. Today, May 1, 1978 is the deadline for submittals. However, any chemical substances manufactured for a commercial purpose between May 1 and 30 days following publication of the initial inventory may be reported when manufactured.

In cooperation with the business and manufacturing areas, E. Handwerk is preparing a document file to support reporting actions taken with emphasis on unique and complex reporting circumstances. Such areas become "gray areas" within a short period of time.

- b) The deadline for the Trademark Inventory has been extended to July 15, 1978. An amendment to the certification statement permits manufacturers of trademarked products to report processed components of the trademark during the 210 day revised inventory reporting period, thereby allowing

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AP00049024

the manufacturer to report trademarks for which he may not be able to certify that all components have been reported for the initial inventory.

APCI will report trademarked chemical substances and utilize the revised inventory reporting period to report components not present on the initial inventory.

3. Substantial Risk - Updated Policy

Corporate Policies has prepared a Standard Procedure (revised) for Substantial Risk Notification. The standard will be distributed to corporate policy manual holders and to individuals on the revised Substantial Risk Notification distribution list.

Highlights of the updated policy are:

- a) Employees fulfill their legal obligation through notification by company procedure.
- b) Persons capable of appreciating the significance of pertinent information are subject to the act.
- c) Notification to the EPA should occur within 15 working days of receipt of information.
- d) Single In Vitro Tests for mutagenicity are not substantial risk items unless, or until, corroborated by additional affirmations.
- e) Emergency incidents of environmental contamination are to be reported by telephone.
- f) Pre January 1, 1977 information is to be reported if it is drawn to our attention since Jan. 1, 1977.
- g) The decision group must notify submitters of the disposition of their notices.

4. TSCA Timetable

a) MID's Role

- (1) Establish a cross-reference to available TSCA related files based on the Chemical Abstracts Service registry number.
- (2) Establish a Chemical substances data base to permit rapid location of data elements concerning reported chemical substances, e.g., confidentiality claims, toxicity data, hazardous properties, etc.
- (3) Prepare TSCA files such that they can also meet the needs of other departments, e.g., Corporate Safety.

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AP00049025

b) Premarket Notification

Rules are expected to be promulgated in the July to September 1978 period. PMN will become effective 30 days after publication of the initial inventory.

- c) C. E. Blades presented an orientation of the areas in which records must be maintained to meet TSCA regulations. Such areas include production data, information reported for the Inventory, adverse reactions, health and safety studies and substantial risk notification. (See Addendum for full text)

- d) C. E. Blades will issue a bulletin on handling of PCB's.

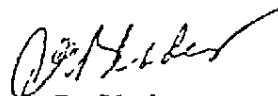
5. Priority List

The Interagency Testing Committee, in April, published a first addendum to the Priority List. This addendum called a "list of 8" contained 4 chemical substances and 4 categories (see Figure 1). The initial list (Figure 2) of 10 contained 4 substances and 6 categories (in fact between 40-50 chemical substances). The TSCA limits the priority list to 50 at any given time. EPA has made an end run on this number through the use of "categories".

Figure 3 illustrates the basis for inclusion of the chemicals and categories on a list for priority testing. The EPA must define testing required within 1 year of list issue or explain why testing is unnecessary. A submission by industry of sufficient data to determine risk could remove need for additional tests.

The next TSCA meeting is scheduled for MONDAY, JUNE 12 at 1:30 P.M.

CEB/EIH/sk
Encls.



C. E. Blades

AP00049026

LIST OF EIGHT (APRIL 1978)

ACRYLAMIDE

64MM LBS., 20,000 WORKERS

* ARYL PHOSPHATES

65MM LBS., - PLASTICIZERS, HYDRAULIC FLUIDS,
LUBRICANTS

* CHLORINATED NAPHTHALENES

LUBRICATING AND CUTTING OIL ADDITIVES, DIELECTRICS

DICHLOROMETHANE

500MM LBS., 9% GROWTH RATE

* HALOGENATED ALKYL EPOXIDES

EPICHLOROHYDRIN 500MM LBS., 50,000-140,000 WORKERS

* POLYCHLORINATED TERPHENYLS

400,000 LBS. IMPORTED 1975 - OBSERVED IN HUMAN
BLOOD >PCB's

PYRIDINE

60MM LBS., 249,000 WORKERS

1,1,1-TRICHLOROETHANE

CLEANING SOLVENT, METALS

630MM LBS., 3MM WORKERS

* CATEGORIES

AP00049027

TITC LIST OF 10
FOR
PRIORITY TESTING

ALKYL PEROXIDES	*
ALKYL PHTHALATES	*
CHLORINATED PARAFFINS	*
CHLOROMETHANE	
CRESOLS	*
HEXACHLORO-1,3-BUTADIENE (HCBD)	
MONO- and DI-CHLOROBENZENES	*
NITROBENZENE	
TOLUENE	
XYLENES	*

* Categories

PRIORITY LIST OF CHEMICALS

(OCT. 4, 1977)

LARGE AMOUNTS RELEASED TO THE ATMOSPHERE

XYLENES

(0.9 MM LBS./YR.)

TOLUENE

(1.0 MM LBS./YR)

CHLOROMETHANE

(1.75 MM LBS./YR.)

LARGE AMOUNTS IN WASTE & AQUATIC ENVIRONMENT

ALKYL PHTHALATES

(PLASTICIZER)

CHLORINATED PARAFFINS

(50 MM LBS./YR)

HEXACHLORO-1,3-BUTADIENE

(BY-PRODUCT, WASTE)

INDUSTRIAL WORKER EXPOSURE SIGNIFICANT

ALKYL EPOXIDES

MONO & DI-CHLORINATED BENZENE

CRESOL

(2 MM WORKERS)

CHLOROMETHANE

(31,000 WORKERS)

WIDELY USED HOUSEHOLD PRODUCTS

NITROBENZENE

(RAPIDLY ABSORBED THRU SKIN & LUNGS)

CHLORINATED PARAFFINS

SUBJECT
D.

3M

CATALOG NO. 15
3M CENTER, ST. PAUL
MADE IN U. S. A.

AP00049029

Talk Presented at TSCA Meeting
May 1, 1978 - C. E. Blades

ISSUES INVOLVED IN COMPLIANCE WITH TSCA --
OTHER REPORTING REQUIREMENTS

The stated purpose of the Toxic Substances Control Act is:

Reduce the risk of potential harm to health
and environment arising from toxic hazards
of chemical substances.

There are many sections in the act. The one we are going to talk about today is Section 8. The title of Section 8 is "Reporting and Retention of Information" (SLIDE 1)

There are 5 subsections to Section 8, as shown on the slide. To get an appreciation for the work load that would be imposed upon industry by virtue of Section 8, it is well to look at the next slide. (SLIDE 2) Here we see a block diagram of what we might refer to as the "industrial unit" or the "company". Within the company, it will be necessary for records to be kept which deal with information which the EPA will, on occasion, and on demand, request be sent to the EPA in the form of reports. Now the kinds of reports which can be demanded by the EPA from industry fall into the five categories which are represented by the five subsections of Section 8. They are:

- (1) Production and related information [8(a)]. Part of the information that has been submitted on the inventory has been requisitioned under the provisions of 8(a) -- namely, volume and site facilities for production of various materials.
- (2) Information on inventory [8(b)]. This is the section of the Act which has been invoked in order to make an inventory of existing chemical substances.
- (3) Information on adverse reactions [8(c)]. We have been concerned for over a year now in collecting information on adverse reactions. I think

AP00049030

May 1, 1978

adverse reaction records. It is not now presently mandated by the law, therefore, but will be shortly. Some of the problems in collecting that kind of information have now surfaced and we will need to address ourselves to that as soon as the rules are promulgated, or before.

Section 8(d), dealing with Health and Safety Studies, have raised some interesting questions. Proposed rules have already issued. These have been instigated by the need to obtain health and safety studies from industry pertaining to the list of 10 substances and categories on the Priority List. It is well to understand that the Interagency Test Committee has recommended to EPA a list of 10 chemical substances and categories of substances which they believe require additional test data in order to evaluate the risk of harm to health and the environment arising from the use of these chemicals in commerce. Within one year of the publication of the list, EPA must take action. The action they take will depend upon the type of information that they receive relative to the hazard descriptions of these products. It would seem to me, therefore, that it is in the interest of industry to submit all test data that is in their hands and not in the hands of the EPA.

In order to write the rule, EPA has probably gone overboard in the sense that they have asked for all health and safety studies known to exist, or in the hands of industry. Not only final reports, but preliminary reports. There is no indication that they want reports on studies that are in progress or contemplated. There is a concern with the request for preliminary information because this could be misleading if placed in the wrong context. I have in my possession some comments that were prepared by the Olin Co. on these rules. They draw attention to two or three facts. (1) There is a feeling that the agency should first request lists of studies, adequately identified so that when requests for the actual study copies are received, EPA will not be deluged with duplicate copies through multiple client studies. There is also a provision for companies to identify studies they know of but do not actually have in their possession. In this case, they are to identify those studies and tell where they can be obtained. Thus, a manufacturer or industrial unit provides EPA with the means to reach into contract laboratories and associations such as CIIT to obtain such data, and by law those reports will have to be provided. Another feature of these rules is that although addressed to the priority list, it will, in fact, form precedence for the requesting of all

AP00049031

May 1, 1978

there is an interplay here between the Substantial Risk Notification, Events are those which would be collected in our records of significant adverse reactions. If a series of events occurs which would lead to a conclusion that a substantial risk existed, then an 8(e) notice could go into the agency. The troublesome part of the Significant Adverse Reaction records is that alleged inter-relationships between reaction on the health or the environment and a cause, as it may be related to a product, must be placed in the record. And there are certain retention times that these must have in the record before they can be disposed of.

- (4) Health & Safety Studies [8(d)] -- The interesting thing about Health and Safety Studies is that they can take two forms -- a list of such studies or the actual studies themselves.
- (5) Substantial Risk Notification [8(e)] -- We now have a company procedure covering this.

Moving through these various sections, looking at the provisions of them, we look at the next slide which gives a synopsis, if you like, of the actual provisions of the act. (SLIDE 3), and as Joanne Egan has been talking about, the need to keep records on chemical substances or products within the company, and the categories of those regulations are spelled out in the law. It will be seen that the production records are only a part of the records that need to be kept under this section of the act. Rules need to be proposed and finalized prior to any serious addressing oneself to this section. We need to be aware of the fact that the records need to be kept but the precise form in which the rules will be written still remains unknown and we tend to sit in a position of suspended animation until those things arise.

We will not discuss Section 8(b). We'll move on to Section 8(c) in the next slide (SLIDE 4) . Here you will see the kinds of records that need to be kept and the time retention for each type. We have wrestled with the definitions of what constitutes a "significant adverse reaction". I am proposing that we back off on that activity for the present, insofar as again here we now realize that rules will have to be promulgated for the keeping of significant

AP00049032

May 1, 1978

health and safety studies under Section 8(d) of the act. It is to be made clear that health and safety studies requests for such reports do not necessarily relate to the priority list. The priority list is providing instigation for the initiation of this reporting system.

On the next slide (6) I have a list of the original "list of 10" chemical substances and categories proposed for priority testing. Those with asterisks are the categories. Now, because of the category system here, we find that in reality this list deals with in the order of 40 to 50 individual chemicals since one cannot test a "category". Therefore, health and safety studies are being requested on the order of 40-50 chemicals from that list. The types of studies that are being requested deal with the types listed on the next slide (7), --carcinogenicity, mutagenicity, teratogenicity, other chronic effects (meaning all tests are of repetitive exposure type) epidemiological studies and environmental effects.

In the next slide (8), we list some of the bases for selection of these materials by the Interagency Testing Committee and you will note that there are a series of chemicals which are released to the atmosphere. These are solvents and rather large quantities go to the atmosphere:

Xylenes	-	0.9 MM lbs.
Toluene	-	1.0 MM lbs.
Chloromethane	-	1.75 MM lbs.

There is a group here that is thought to be getting into wastes and aquatic environment, through leaching etc. There are some that are primarily related to industrial worker exposure and some in the household.

In the next slide (9) I have listed the second list of priority chemicals for testing. In this case there are four chemical substances and four categories. I haven't got a breakdown as to how many health and safety studies this will require for submittal. You will notice that there are no Air Products & Chemical products on here except some of those which are processed by the Specialty Gases Division and you need to take note that these things are on this list.

AP00049033

May 1, 1978

Of interest is a report of comments made by two citizens groups relative to the proposed health and safety study rules. The first is made by the Environmental Defense Fund. In their comments, they claim that EPA has not gone far enough in requesting health and safety studies. They suggest that some studies may exist which are known to company officials but are not reduced to writing. These should be submitted they say. Secondly, the rule applies to juridical persons. EDF claims that this is not consistent with the 8(e) policy statement. They propose that the requirement to submit health and safety studies be extended to all officers who are responsible and have authority for 8(d) responsibilities. The intent of that would be to make individual employees within companies (especially toxicologists and related professions) personally responsible to submit reports to the EPA under health and safety studies.

The Citizens for a Better Environment (CBE) suggests that EPA collect all health and safety studies on a list of 10, not just those pertaining to the effects listed. You notice that there were six different categories of effects (types of studies) that were requested. This organization is suggesting that health and safety studies submittals not be restricted to those. This comment is made in the following context, "The notorious reluctance of industry to submit data on health hazards". OSHA's Eula Bingham has made a comment which suggests that a generic rule be formulated under which new studies could be inserted at any time. I am not sure just exactly what that means. It would appear that if polynuclear hydrocarbons were a subject of health and safety study submittals, then all health and safety studies that were run at a future date which dealt with any kind of a polynuclear hydrocarbon would automatically be required to be added to the pot. She also urged that the rule be enlarged immediately to apply to chemicals other than those which are on the Priority List so that EPA may have at its disposal information on spills or emergency incidents so that they may know how to deal with those matters.

The foregoing is presented to emphasize the fact that extensive requirements are to be imposed upon industry for the keeping of records dealing with the chemicals which are produced and manufactured within the industrial unit. It is easy to see that maintaining of these records at an up-to-date status and in a format whereby requests can be answered in some reasonable period of time, suggests that the data be placed on the computer in a systematic way. It is this forecast which is leading many industrial units in the country to seriously consider the

AP00049034

May 1, 1978

placing of all data relating to their chemical products (and especially that which is mandated by the act) in a computer storage system. I think that some form of this type needs to be adopted by Air Products.

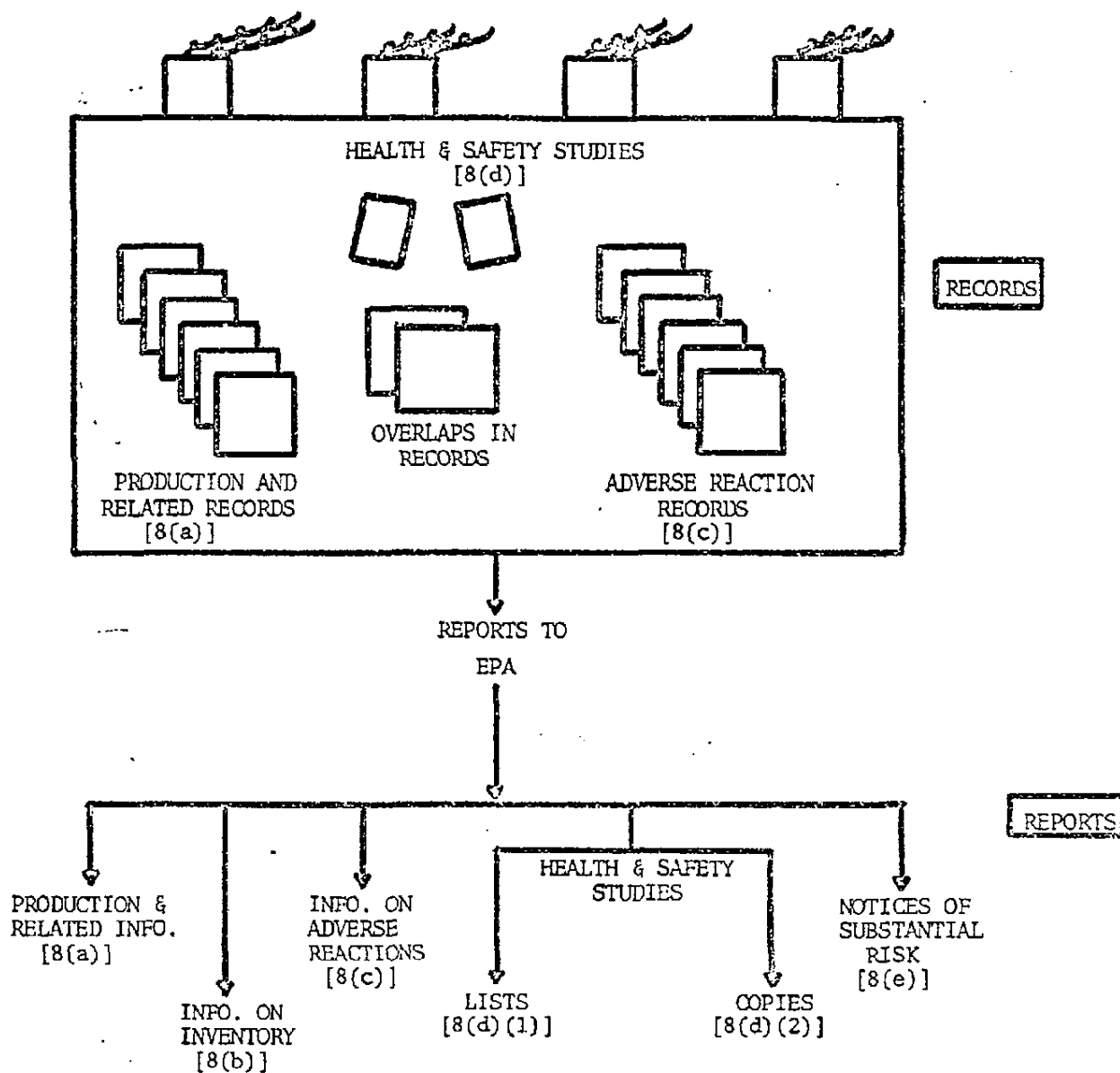
AP00049035

SECTION 8

REPORTING AND RETENTION OF INFORMATION

- (a) REPORTS
- (b) INVENTORY
- (c) RECORDS OF SIGNIFICANT ADVERSE REACTIONS
- (d) HEALTH AND SAFETY STUDIES
- (e) SUBSTANTIAL RISK NOTIFICATION

INDUSTRIAL RECORDKEEPING & REPORTING
FOR EXISTING CHEMICALS



AP00049037

SECTION 8(a)

(a) REPORTS

- (1) MAINTAIN RECORDS (TO DOCUMENT REPORTS)
REQUIRED BY EPA TO ENABLE ENFORCEMENT
OF THE ACT.

RULES REQUIRED.

PRIME THRUST AT CHEMICAL SUBSTANCES --
NOT MIXTURES.

- (2) INCLUDES:

IDENTIFICATION INFORMATION

CATEGORIES OF USE

AMOUNTS MANUFACTURED FOR EACH CATEGORY

BY-PRODUCTS FROM MANUFACTURE OR USE

DATA ON ENVIRONMENTAL & HEALTH EFFECTS

EXPOSURE DATA

METHOD OF DISPOSAL

SECTION 8(c)

RECORDS OF SIGNIFICANT ADVERSE REACTIONS

MAINTAINED AS RECEIVED BY A MANUFACTURER, PROCESSOR
OR DISTRIBUTOR FROM ANY SOURCE

EMPLOYEE HEALTH

30 YEARS

CONSUMER ALLEGATIONS

OF PERSONAL INJURY
OF HARM TO HEALTH

REPORTS OF OCCUPATIONAL DISEASE

OF OCCUPATIONAL INJURY

REPORTS OR COMPLAINTS OF

INJURY TO ENVIRONMENT

5 YEARS

AP00049039

HEALTH AND SAFETY STUDIES

- LISTS OF STUDIES EITHER
IN POSSESSION
or
KNOWN TO EXIST (and where)
- COPIES OF STUDIES

AP00049040

TITC LIST OF 10
FOR
PRIORITY TESTING

ALKYL PEROXIDES	*
ALKYL PHTHALATES	*
CHLORINATED PARAFFINS	*
CHLOROMETHANE	
CRESOLS	*
HEXACHLORO-1,3-BUTADIENE (HCBP)	
MONO- and DI-CHLOROBENZENES	*
NITROBENZENE	
TOLUENE	
XYLENES	*

* Categories

STUDY TYPES(43 FR 4073, Jan. 31, 1978)

CARCINOGENICITY

MUTAGENICITY

TERATOGENICITY

OTHER CHRONIC EFFECTS

EPIDEMIOLOGICAL STUDIES

ENVIRONMENTAL EFFECTS

AP00049042

PRIORITY LIST OF CHEMICALS

(OCT. 4, 1977)

LARGE AMOUNTS RELEASED TO THE ATMOSPHERE

XYLENES

(0.9 MM LBS./YR.)

TOLUENE

(1.0 MM LBS./YR)

CHLOROMETHANE

(1.75 MM LBS./YR.)

LARGE AMOUNTS IN WASTE & AQUATIC ENVIRONMENT

ALKYL PHTHALATES

(PLASTICIZER)

CHLORINATED PARAFFINS

(50 MM LBS./YR)

HEXACHLORO-1,3-BUTADIENE

(BY-PRODUCT, WASTE)

INDUSTRIAL WORKER EXPOSURE SIGNIFICANT

ALKYL EPOXIDES

MONO & DI-CHLORINATED BENZENE

CRESOL

(2 MM WORKERS)

CHLOROMETHANE

(31,000 WORKERS)

WIDELY USED HOUSEHOLD PRODUCTS

NITROBENZENE

(RAPIDLY ABSORBED THRU SKIN & LUNGS)

CHLORINATED PARAFFINS

SUBJECT

D.

3M

CATALOG NO. 15 -
3M CENTER, ST. PAUL
MADE IN U. S. A.

AP00049043

LIST OF EIGHT (APRIL 1978)

ACRYLAMIDE

64MM LBS., 20,000 WORKERS

* ARYL PHOSPHATES

65MM LBS., - PLASTICIZERS, HYDRAULIC FLUIDS,
LUBRICANTS

* CHLORINATED NAPHTHALENES

LUBRICATING AND CUTTING OIL ADDITIVES, DIELECTRICS

DICHLOROMETHANE

500MM LBS., 9% GROWTH RATE

* HALOGENATED ALKYL EPOXIDES

EPOCHLOROHYDRIN 500MM LBS., 50,000-140,000 WORKERS

* POLYCHLORINATED TERPHENYLS

400,000 LBS. IMPORTED 1975 - OBSERVED IN HUMAN
BLOOD >PCB'S

PYRIDINE

60MM LBS., 249,000 WORKERS

1,1,1-TRICHLOROETHANE

CLEANING SOLVENT, METALS

630MM LBS., 3MM WORKERS

* CATEGORIES

AP00049044

Air Products

RECEIVED

APR 26 1978

LAW DEPT.

Date April 24, 1978

INTEROFFICE
MEMORANDUM

Subject Agenda For TSCA Meeting

May 1, 1978

To Distribution

From C. E. Blades

(Location, Organization, or Department)

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Distribution: W. M. Smith - E. I. Handwerk
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G. Frieling

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The next TSCA Compliance Committee Meeting will be held on MONDAY, MAY 1, 1978
at 1:30 P.M. in Conference Room 113G, Main Office Building.

The agenda will be as follows:

1. Approval of Minutes TSCA Committee Meeting, March 13, 1978.
2. Report on Inventory
 - (a) Existing Chemical Substances
 - (b) Trade Marks Inventory
3. Substantial Risk
 - (a) Distribution List Certification
 - (b) Revision in accord with March 16, 1978 Policy Statement
 - (c) Industry Activity Report.
4. EPA's TSCA Timetable
 - (a) The record keeping/reporting priority (Section 8)
 - (b) Impact on APCI
 - (c) MID's role and plans
 - (d) Premarket Notification, Inventory Publication, -- the activity and prognosis

E. I. Handwerk
C. E. Blades

continued.....

AP00049045

5. Priority List Development

(a) Prognosis

(b) Health & Safety Study Rules.

CEB:sk


C. E. Blades

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