



CHEMICAL MANUFACTURERS ASSOCIATION

June 5, 1981

TO: Ethylene Program Panel
SUBJECT: Ethylene Dichloride Reporting Rule Proposal

Enclosed please find an advance copy of an EPA draft proposal on TSCA, Section 8(a) Reporting Rule for Ethylene Dichloride. Publication in the Federal Register is expected to occur shortly at which time we will have the opportunity to formally comment.

Please let Mr. John Murphy or me know if you think it is advisable to respond to the proposal when it comes out in the Federal Register. Mr. John Murphy can be reached at (203)222-3493 and I can be reached at (202)887-1192.

Sincerely,

Has

Hasmukh C. Shah, Ph.D
Director
Biomedical and Environmental
Special Programs

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Environmental Affairs

APL
Pls
review
and
provide
some
comments -
Let's
discuss
6/13/81

THIS DRAFT IS
NOT TO BE
CITED OR QUOTED

ENVIRONMENTAL PROTECTION AGENCY

(40 CFR PART 704)

[OPTS-82006]

1,2-DICHLOROETHANE (ETHYLENE DICHLORIDE, EDC)

REPORTING OF PROCESSING INFORMATION

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: This rule, proposed under section 8(a) of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2607(a), would require

certain processors of 1,2-dichloroethane (ethylene dichloride, EDC) CAS #107-06-2, to identify themselves and to report the

intended uses of the EDC-containing products they make. These

processors would also report quantities of EDC obtained and used

for each of their processes or products. EPA wishes to evaluate whether dispersive uses of EDC pose

an unreasonable risk to health or the environment. Information reported under this rule will be considered by EPA in assessing

potential risks and determining whether regulation of certain dispersive uses of EDC is needed.

DATES: Written comments on this proposal must be postmarked on or before (insert date 60 days after date of publication in the FEDERAL REGISTER). Written comments should bear the

document control number (OPTS-82006) and should be submitted to:

Document Control Officer,

Office of Pesticides and Toxic Substances (TS-793),

80T-1552

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Environmental Protection Agency,

Rm. E-105,

401 M Street, SW,

Washington, DC 20460.

All written comments filed pursuant to this notice will be available for public inspection at the above address from

8:00 a.m. to 4:00 p.m. Monday through Friday, except legal

holidays. Interested persons may also request time to meet with

EPA staff responsible for developing this proposed rule. Such

meetings will be held (insert date 5 days after the end of

written comment period), in Room , Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

John B. Ritch,

Industry Assistance Office (TS-799),

Environmental Protection Agency,

Rm. E-125,

401 M S , SW,

Washington, D.C. 20460,

Toll free: (800-424-9065),

In Washington, DC: (554-1404).

SUPPLEMENTARY INFORMATION:

I. BACKGROUND

A. Production and Use

1,2-dichloroethane (EDC) is a high volume chemical with an estimated annual production of over five billion kilograms.

Most of the EDC is manufactured domestically and used as a

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feedstock in the production of other chemicals, with the vast majority used in the production of vinyl chloride monomer, and other organic chemicals, including trichloroethylene, perchloroethylene, vinylidene chloride and ethylene amines. In addition, EDC has been employed for several miscellaneous, "dispersive" uses. "Dispersive" uses are those in which some, or all, of the substance is eventually released into the environment. Such uses include additives for motor-vehicle fuels, grain fumigants, other pesticidal applications, solvents, penetrating oils, extractants, and cleaning agents. Data available from the National Institute for Occupational Safety and Health (NIOSH), the Consumer Product Safety Commission (CPSC), and from commercial product data bases indicate that EDC has been used in a number of diverse product categories. However, it is unknown whether EDC is presently used in these ways, and if so, in which products or processes.

B. Toxic Effects

There is evidence that exposure to EDC may present risks to health and the environment. Toxic effects of EDC to humans and animals have been reported in the scientific literature by a number of investigators and the data have been extensively reviewed by NIOSH. In 1975, NIOSH recommended that the present Occupational Safety and Health Administration (OSHA) exposure standard of 50 ppm be reduced to 5 ppm over a 40-hour workweek to prevent, or minimize, disorders of the skin, eye, lung, liver,

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kidney and heart which could result from exposure to EDC. [See "Criteria for a Recommended Standard -- Occupational Exposure to Ethylene Dichloride (1,2-Dichloroethane)", DHEW (NIOSH) Publication No. 76-139, 1976].

More recently, EDC was found to be carcinogenic in two rodent species in National Cancer Institute (NCI) bioassay studies ~~and mutagenic in other studies~~. On the basis of these findings, in September 1978, NIOSH issued a recommendation to lower the occupational exposure standard for EDC still further to 1 ppm. [See "Revised Recommended Standard -- Occupational Exposure to Ethylene Dichloride (1,2-Dichloroethane)", DHEW (NIOSH) Publication No. 78-211, September, 1978.]

The Office of Pesticides and Toxic Substances (OPTS) and several other program offices within EPA are currently assessing the potential for human exposure to EDC and for its release into the environment. The information to be collected under this rule will contribute significantly to these assessments.

II. THIS RULE

The production, release, and potential for exposure to EDC during its manufacture and use as a feedstock -- particularly in the production of vinyl chloride -- have been fairly well characterized in existing data available to EPA. However, few data are available to the Agency on the miscellaneous dispersive uses of EDC. The purpose of this rule is to identify persons who process EDC for dispersive uses, the nature of such uses and the quantity of EDC associated with each use, so that subsequent

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assessments of the risks associated with dispersive uses of EDC can be focused on the most significant of these uses.

EPA, other Federal agencies, and their contractors have conducted a number of studies of EDC and its uses. The studies revealed that current information concerning most specific uses of EDC (other than as a feedstock) is not readily available in the trade and technical literature or from other public data sources, partly due to the fact that miscellaneous dispersive uses of EDC represent only a small fraction of the EDC market.

Also, industry has been reluctant to provide data necessary for these studies in large part because the use and distribution patterns of EDC are often considered proprietary. The contractors have documented numerous previous dispersive uses of EDC, but have been unable to substantiate whether and to what extent EDC is still so used.

The specific use of approximately five million kilograms of the annual EDC domestic production remains unidentified. These five million kilograms are believed to go into dispersive uses (other than pesticidal and fuel additive applications) and may present a potential for widespread exposure from releases in the workplace and into the environment. The GCA Corporation, in a study for EPA (see PUBLIC RECORD -- Item 4), estimated that dispersive uses of EDC, including pesticidal and leaded gasoline additive applications, may account for as much as 33% of the total annual amount of EDC released to the environment. However, GCA was unable to substantiate specific dispersive uses or to verify this estimate. Similarly, a study by Battelle

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Laboratories, under contract to the CPSC, identified several categories of consumer products which formerly contained EDC. However, Battelle was unable to verify current usage of EDC in consumer products because products may have been reformulated to eliminate EDC and because this information is considered proprietary by industry.

Other contractor studies of EDC conducted for EPA were also unable to adequately document dispersive uses, exposures, and releases of EDC. These studies included a review of EDC as an environmental pollutant prepared by Oak Ridge National Laboratory in April 1979, and a Level 1 Materials Balance Study prepared by JRB Associates in February 1980. These documents are available in the public record for this rule.

Information about EDC usage was also obtained from NIOSH. Some time ago, NIOSH conducted a National Occupational Hazard Survey (NOHS). The survey indicated widespread exposure to EDC in a large number of diverse processing or industrial operations. The following table, "EDC -- Dispersive Uses and Industrial Applications", summarizes potential EDC usage identified by the Survey.

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EDC -- DISPERSIVE USES AND INDUSTRIAL APPLICATIONS

Examples of Dispersive Uses of EDC Identified
in the National Occupational Hazard Survey (NOHS)

Additive
Adhesive
Aerosol cleaners
Carburetor cleaners
Cement-glue
Cleaning compounds
Coatings
Cutting oils
Degreasers
Disinfectants
Drain openers
Enamels
Fabric rust removers
Fumigants
Ink removers
Insecticides
Lubricants
Paints
Penetrating oils
Pigments
Reagents
Rust inhibitors
Sealants
Solvents

Examples of Industrial Processing
Applications in Which EDC may be Utilized

Adhesives Formulators
Asphalt Processing
Bakelite Processing
Bitumen Processing
Camphor Processing
Cosmetics Manufacture
Cellulose Acetate Dispersion
Cellulose Ester Dispersion
Dry Cleaning Applications
Degreasing Operations
 Textile industry
 Petroleum industry
 Electronics industry
Extractant
 Soybean oil
 Fish protein
 Caffeine
 Dyes
 Camphor

Milk Preservation
Ore Processing
Paint Solvation and Stripping
Pesticide Processing
Petroleum Refining
Pharmaceuticals
Photocopying Processes
Photography
Resins Processing
Rubber Processing
Textile Processing
 Nylon
 Viscose rayon
Varnish Diluent
Water Softening

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On the basis of that survey, NIOSH estimated that ". . . approximately 1.5 million workers in more than 148,000 workplaces are potentially exposed to EDC -- some 200,000 of whom are estimated to be continuously exposed to EDC in the workplace."

However, the NOHS survey was not designed to specifically quantify use and exposure of EDC in the workplace. Rather, based on a large sample of observations of chemicals used in the workplace, the survey was intended to serve as a statistical projection of potential use and exposure to chemicals generally, including EDC, in plant sites throughout the country. From observations of EDC in the workplace as reported in the survey, it appears that approximately 90 percent of the reported use was determined by "generic resolution" which consisted of accepting the product use category noted by the investigator and then making a "best guess" estimate of which chemicals might be present in such products. For example, where an observed substance might have been a solvent, all likely solvent possibilities were recorded by the investigator. If the specific solvent could not be positively identified at the plant site or by subsequent manufacturer verification, the exposures to this solvent may have been counted as exposure to each of the possible solvent substances. Therefore, the NOHS data may represent an overestimate of EDC use.

III. USES OF REPORTED INFORMATION

Data reported under this rule will be used by the Office of Pesticides and Toxic Substances to support further investigation of the need for TSCA control action.

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Under this rule, processors of EDC [other than for feedstock and other exempted uses specified in §704.85(d)(2)] will identify themselves, the amount of bulk EDC they obtain, the mixtures or other products into which they incorporate the EDC, the function EDC serves in those products, and the amount of EDC contained in such products. The Agency will use these data in several ways. The processor and product identity information will be valuable in itself. It will show the breadth of the EDC processor population and the variety of mixtures and products currently produced. From the processor and product identity information, EPA can develop a more detailed picture than presently exists to determine and quantify points of potential environmental release resulting from dispersive EDC usage. The reports of amounts of EDC obtained, when taken together with other available data, will assist the Agency in drawing a comprehensive picture of EDC consumption.

Quantity information will also be helpful in estimating potential worker and general population exposure from dispersive uses and in assessing the potential impact of any control action. Finally, knowing the kinds of mixtures and other products which contain EDC and the function EDC serves in these products will permit assessments of the availability of substitutes.

The section 8(a) data may also be used by other EPA program offices and other Federal agencies. For example, the Office of Air, Noise, and Radiation, and the Office of Water and Waste Management are both assessing the need for new or revised

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standards for environmental release of EDC. The inventory of processors and plant sites which will result from this rule will be useful in identifying potential sources of EDC release from sites other than those of EDC manufacturers.

CPSC, through contract efforts, has been unable to identify any substantial current use of EDC in consumer products. If the data reported under this rule should identify products containing EDC which might have potential consumer use, this information will be shared with CPSC.

OSHA has expressed interest in data identifying the number and location of sites where EDC is actually processed and data relating to quantities used in the workplace. Such data may be used in a review of the EDC occupational exposure standard.

IV. WHAT MUST BE REPORTED

Processors are required to report EDC processing for each plant site and each EDC-containing product on EPA Form _____, "Processing of 1,2-Dichloroethane (Ethylene Dichloride, EDC)". Processors would identify the company, plant site address where EDC is processed, telephone number, Dun & Bradstreet Number, SIC numbers, and the name of a technical contact person. In addition, they must report the intended function of EDC in the mixture or other product, whether the product is intended for industrial or consumer use, and identify any mixtures or products into which EDC is incorporated.

Processors would also list quantities of EDC obtained, the number of product units produced, the size and type of containers

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or packages in which the EDC-containing product is distributed, and the weight of EDC in each product unit.

V. WHO REPORTS

This rule applies, with certain exclusions, to persons who processed EDC anytime during 1978-1980. These are persons who prepare EDC, after its manufacture, for distribution in commerce, in the same or a different form as they receive it, or as part of a product that contains EDC. Persons who themselves manufacture or import bulk EDC and subsequently process it, must report as processors.

The following are hypothetical examples of EDC processors and the subject of their reports. They are included here for illustrative purposes.

1. A person who manufactures EDC and incorporates it into a paint remover to be sold to consumers would report about the incorporation of the EDC into the paint remover.
2. A person who obtains EDC and incorporates it as a solvent or ink carrier in the wick or cartridge of felt tip pens would report about incorporation of the chemical into the felt.
3. A person who obtains EDC and incorporates it into a chemical mixture to be sold as an industrial cleaning agent would report about incorporation of EDC into the mixture.
4. A person who obtains bulk EDC and repackages it in smaller containers for distribution in commerce would report about the EDC repackaging activity.

Several classes of processors are excluded from reporting under this rule. The major class of processors who are excluded

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are those who react EDC to make other chemical substances. Thus, for example, persons who produce vinyl chloride monomer from EDC, are excluded from this rule.

Also excluded are persons who process EDC for use in fumigants or other pesticides registered under the Federal Insecticide, Fungicide and Rodenticide Act or for use as an additive to motor vehicle fuels reported under the Clean Air Act, 42 U.S.C. 1857f-6c and 1857g. However, persons who process EDC as a fuel additive (e.g., in aviation fuels or consumer products) and do not report under the Clean Air Act are subject to this rule. Additional exclusions from reporting include persons who process EDC solely for research and development, who process EDC as an impurity, or who process a formulated mixture containing EDC.

Small processors of EDC who employed ten or fewer full-time employees in 1980, are also exempt from the rule. We estimate that over 40 percent of the potential respondents who are not otherwise excluded will be exempted as a result of this provision, while firms that account for approximately 95 percent of employees and sales will still be included. This estimate is based upon figures compiled by Dun & Bradstreet for the Small Business Administration. The estimate is further explained in a memorandum titled "Small Business Analysis", which is part of the public record of this rule. The Agency believes that this exemption, in conjunction with the other exclusions above, will greatly reduce the reporting burden, yet enable EPA to obtain sufficient information to develop a reasonably comprehensive

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picture of EDC uses and determine exposures and release potentials in processing EDC.

Section 9(a) of TSCA states that reporting by manufacturers or processors of mixtures may be required only when the Administrator determines that it is "necessary for the effective enforcement" of TSCA. This regulation will require reporting from persons who mix EDC with other chemicals to formulate products that are then sold for dispersive uses. For purposes of this rule, EPA views these persons as processors of the chemical substance EDC since they prepare the chemical for distribution in commerce in the same or in a different form or physical state from that in which it was received. The Agency is not focusing its investigation on the potential health effects of these mixtures per se, but on the effects of the chemical substance, EDC. The Agency, therefore, is not required to determine whether the information on EDC to be collected from these persons is "necessary for effective enforcement" of TSCA. EPA has nevertheless made this determination for this rule. The Agency proposes to require the reporting of information essential to completing the picture of the sources, utilization, and environmental release of EDC. Without this information, the Agency would be unable to fill gaps in its assessment of the risks associated with EDC. Therefore, to the extent that this rule would require information about EDC to be reported by persons who use EDC to formulate mixtures, the Administrator finds that it is necessary for the effectiveness of this rule and, therefore, for effective enforcement of TSCA.

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VI. REPORTING YEAR

The reporting years are 1978, 1979, and 1980. Persons who processed EDC during 1980 would report only for 1980. However, batch processors who did not process EDC during 1980 would report about the most recent year in which they processed EDC, i.e., 1978 or 1979.

VII. REPORTING BURDEN

The composition of the EDC processing industry subject to this rule is not defined in any source available to EPA. Therefore, the Agency can only estimate the number of EDC processors and the costs which may result from reporting EDC processing.

The industry-wide NOHS survey conducted several years ago indicated that EDC might be widely used in many industrial applications and processes. Based on the survey, NIOSH projected that EDC may be used in approximately 148,000 plant sites. Reasons for believing that the NOHS data may be an overestimate are discussed elsewhere in this preamble. It is also important to note that the NOHS survey was concerned with the number of plant sites at which EDC might be used. This number of users of EDC is expected to be considerably greater than the number of processors of EDC -- the only persons to whom this rule applies.

While the NOHS data are primarily estimates of occupational exposures to EDC, identifying only a few specific EDC products, the survey does provide information about potential uses in industrial applications and processes. In order to obtain a

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better estimate of numbers of potential EDC processors, we studied data from the Bureau of Census, 1977 Census of Manufactures. We examined Standard Industrial Classification (SIC) Categories of Manufactures to identify those SIC categories of manufactures which represent the industrial applications identified by NIOSH/NOHS. We identified approximately 30 categories as those most likely to include establishments where EDC may be processed.

Given the small percentage (about 10 percent) of plant sites where EDC use was actually identified by the NOHS survey, and given the classes of processors excluded from this rule, we concluded that it is reasonable to assume that 10 percent of the establishments within the 30 selected SIC categories would be a maximum estimate of the number of processors of EDC. Census of Manufactures data indicate that there are approximately 10,000 establishments with 20 or more employees within the selected SIC categories. For proprietary reasons, Census of Manufactures data are not available to EPA for establishments with fewer than 20 employees. Therefore, the actual number of establishments in the selected SIC categories is probably somewhat greater than 10,000. However, on the basis of the available Census data about numbers of establishments (approximately 10,000), we estimate that a maximum of 1,000 processors not otherwise exempt may be subject to this rule. This figure could be as much as a ten-fold overestimate. The fact that EPA and its contractors have been unable to discover the extent of the dispersive use of EDC may reflect a significant decline in processing for these uses.

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Comment is requested on the potential number of respondents to this rule.

Since only a small segment of industrial activity involving EDC will be affected by this reporting requirement, the reporting burden is expected to be small. The following cost estimates are based on the assumption that each respondent will submit only one form. This assumption and cost estimate will be revised if necessary based on comments received during the comment period. We estimate that completing the one-page form will take no more than 4.5 hours/form at a cost of \$135 per form. This would result in a maximum estimated overall cost of \$135,000, for 4500 reporting hours based on an estimate of 1000 respondents, and a minimum of \$13,500 and 450 hours if there are 100 respondents.

A more detailed description of the reporting burden calculations is contained in the "Reports Impact Analysis", an internal EPA report that is included in the public record for this rule. Copies may be obtained from the Industry Assistance Office at the address and telephone number given at the beginning of this notice.

Comment is requested on these reporting estimates. EPA recognizes that the total reporting hour and cost projections are estimates based on scanty and incomplete data. The Agency will consider any evidence of the size of the respondent group, the number of forms to be submitted per respondent, and of the costs to complete the form that are submitted in response to this proposal, when developing the final reporting impact analysis.

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This rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. Therefore, it is not subject to the requirements of the Regulatory Flexibility Act, PL 96-354. As required by the statute, EPA is consulting the Office of Advocacy, Small Business Administration. As described above in Section V, the Agency is proposing to exempt small businesses from the requirements of this rule. The proposed definition of small businesses would exempt approximately 40 percent of the entities which would otherwise be subject to the rule. The Agency is requesting public comment on whether this exemption is appropriate for this information gathering activity. Should the Agency adopt this small business exemption or an alternative exemption after consideration of comments, then the rule will have no impact on the exempted small entities. Moreover, the Agency believes that the cost of reporting under this rule is not likely to have a substantial impact on any entity potentially subject to the rule.

VIII. CONFIDENTIALITY

Firms may assert a claim of business confidentiality for any information submitted in response to this rule. EPA is aware of the need to maintain the confidentiality of any legitimate trade secret. Confidential information will be safeguarded as provided in the "TSCA Confidential Business Information Security Manual" which can be obtained by calling the information number given at the beginning of this notice. Specific provisions for making confidentiality claims are contained in the proposed rule and form.

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IX. SUNSET PROVISIONS

Internal EPA regulations state that any new reporting requirement will contain a provision for its repeal within five years after promulgation. This reporting requirement will terminate within five years after its promulgation.

X. PUBLIC MEETINGS

Following the written comment period, EPA personnel responsible for developing this proposal will be available to meet on (insert date 5 days after close of written comment period) with interested persons from companies, organized labor, trade associations, and citizens organizations to discuss this proposed rule. These meetings will be held in Room , Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460. The Agency will make transcripts or summaries of such meetings for inclusion in the public record for this rule.

All meetings will be open to the public. EPA intends to limit active participation in the meetings to those persons requesting the session and EPA personnel designated for the session.

To request time for a meeting, interested persons should call EPA's Industry Assistance Office, toll-free at 800-424-9065, or 554-1404 in the Washington, D.C. area.

XI. PUBLIC RECORD

EPA has established a public record for this rulemaking (Docket Number OPTS-82006). The record, along with a complete index, is available for inspection in the OPTS Reading Room;

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Rm. E-105, 401 M St., SW, Washington, DC 20460, from 8:00 a.m. to 4:00 p.m. on Monday through Friday, except legal holidays. This record contains the basic information that the Agency considered in developing this proposed rule. The Agency will supplement the record with additional information as it is received. The record includes the following:

1. This proposed rule.
2. NIOSH "Occupational Exposure to Ethylene Dichloride (1,2-Dichloroethane)", DHEW (NIOSH) Publication No. 76-139, 1976.
3. NIOSH "Revised Recommended Standard -- Occupational Exposure to Ethylene Dichloride (1,2-Dichloroethane)", DHEW (NIOSH) Publication No. 78-211, September 1978.
4. EDC Status Report from Rules Development Branch, dated July 1980.
5. Draft Final Report, "1-2-Dichloroethane -- Technical Control Options Analysis", submitted to EPA, OPTS, Control Action Division by GCA Corporation, April 1980.
6. Final Draft -- "Report on 1,2-Dichloroethane" submitted to EPA, OPTS, PID, by Koba Associates, August 12, 1980.
7. "Investigations of Selected Environmental Pollutants: 1,2-Dichloroethane", submitted to EPA, OPTS, Assessment Division, by Oak Ridge National Laboratory, April 1979.
8. "Materials Balance Study -- 1,2-Dichloroethane, Level 1 -- Preliminary", submitted to EPA, OPTS, Survey & Analysis Division, by JRB Associates, Inc., February 1980.

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9. Reports Impact Analysis: Reporting Processing of 1,2-Dichloroethane. (Ethylene Dichloride, EDC).

10. Small Business Analysis Memo, prepared by OPTS, AD, CIRB dated November 1980.

EPA anticipates adding to the rulemaking record the following types of information:

1. All comments on the proposed rule.
2. All relevant support documents and studies.
3. Records of all substantive communications between EPA personnel and persons outside the Agency concerning the proposed reporting rule. (This does not include inter- or intra-agency memoranda unless specifically noted in the index of the rulemaking record.)
4. Minutes, summaries, or transcripts of any public meetings, if held.
5. Any factual information considered by the Agency in developing the rule.

EPA will designate the complete rulemaking record, as prescribed by section 19(a)(3) of TSCA, on or before the date the regulation is promulgated, and will accept additional material for inclusion in the record at any time between this proposal and such designation. The final rule will also permit persons to point out any errors or omissions in the record.

EPA has determined that this document does not contain a major proposal that requires preparation of a Regulatory Analysis under Executive Order No. 12044.

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Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order, or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized". I have reviewed this regulation and determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

Date

Administrator

It is proposed that proposed 40 CFR Part 704 be amended by adding a proposed new section to read as follows:

Sec. 8(a). PL 94-469, 90 Stat. 2029 (15 U.S.C. 2607(a)).

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§704.85 1,2-Dichloroethane (Ethylene Dichloride, EDC);

Reporting of Processing Information

(a) Scope. This rule requires processors of EDC, except as noted in paragraph (d)(2) of this section, to identify themselves and report: the identity of any mixtures or other products into which they incorporate EDC; the function that EDC serves in such mixtures or products; the quantity of EDC processed; and the number of product units produced annually.

(b) Compliance. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to submit information required under this rule. Violation of the requirements of this rule may result in civil penalty or criminal prosecution, as provided under sections 15 and 16 of TSCA. In addition, under section 17, the Government may seek judicial relief to compel submission of required information.

(c) Definitions. The definitions set forth in the Toxic Substances Control Act section 3 apply for this rule. In addition, the following definitions are provided for the purposes of this rule:

(1) "EDC" means all physical forms of the chemical substance, 1,2-dichloroethane (ethylene dichloride), CAS Registry No. 107-06-2, and includes all commercially available grades.

(2) "EPA" means the United States Environmental Protection Agency.

(3) "Feedstock" use means those uses in which EDC is transformed by chemical reaction in the synthesis of other chemical substances.

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(4) "Impurity" means a chemical substance which is unintentionally present with another chemical substance.

(5) "Known to or reasonably ascertainable" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden or cost.

(6) "Person" means any individual, firm, company, corporation, joint venture, partnership, proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency, or instrumentality of the Federal Government.

(7) "Process for commercial purposes" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(8) "Processor of EDC" for purposes of this rule means any person who processes EDC by incorporating it into a mixture or other product, or repackages it for distribution in commerce.

(9) "Site" means a contiguous property unit. Property divided by a public right-of-way shall be considered one site.

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There may be more than one manufacturing plant on a single site.

(10) "Small processor" means for this rule a company which employed no more than 10 full-time employees at any one time in 1980.

(11) "TSCA" means the Toxic Substances Control Act.

(d) Who Must Report. (1) Processors of EDC who processed EDC at any time during 1978-1980, except as noted in paragraph (d)(2) of this section, must fill out and submit a separate form for each EDC containing mixture or product they make. The information on the form shall be information that is known to or reasonably ascertainable by the submitter. Persons who processed EDC during 1980 should report only for 1980. Persons who are batch processors and did not process EDC during 1980 should report the required information for the most recent year (i.e., 1978 or 1979) in which they processed EDC.

(2) The following processors of EDC are not subject to this section:

(i) Persons who process EDC solely as a feedstock in their production of other chemical substances including polymers.

(ii) Persons who process EDC solely for use as a motor vehicle fuel additive subject to reporting under the Clean Air Act, 42 U.S.C. 1857f-6c and 1857g.

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(iii) Persons who process EDC solely for use in fumigants or other pesticidal products registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C §136 et. seq.

(iv) Persons who are small processors of EDC.

(v) Persons who process EDC solely as an impurity.

(vi) Persons who process EDC solely for research and development purposes.

(vii) Persons who process formulated mixtures which contain EDC.

(e) Schedule for reporting.

(1) Persons subject to reporting under paragraph (d) of this section must submit the required data on EPA Form _____ within 30 days after the effective date of the rule.

(f) Where to obtain and submit forms.

(1) EPA Form _____ can be obtained by writing or telephoning:

Industry Assistance Office,

Office of Pesticides and Toxic Substances (TS-799),

Environmental Protection Agency,

Rm. E-125,

401 M St., SW,

Washington, DC 20460,

Toll free: (800-424-9065),

In Washington, DC: (554-1404).

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(2) Completed EPA Form _____ must be mailed to:

Document Control Officer,
Office of Pesticides and Toxic Substances (TS-793),
Environmental Protection Agency,
Rm. E-105,
401 M St., SW,
Washington, DC 20460,
Attn: EDC Reporting.

(g) Confidentiality.

(1) Any person submitting a document under this rule may assert a business confidentiality claim covering all or any part of the submitted material. Any information covered by a claim will be disclosed by EPA only as provided in procedures set forth in 40 CFR Part 2.

(2) A business confidentiality claim for any item reported on EPA Form _____ must be made by checking the appropriate box on Form _____ and by signing the certification statement as specified in the form. By signing the certification statement, the claimant attests to the truth and accuracy of the four statements contained in the form instructions.

(3) If no claim accompanies the notice at the time it is submitted to EPA, the notice will be placed in an open file available to the public without further notice to the respondent.

(h) Reporting processing of EDC. The following EPA Form _____, "Processing of 1,2-Dichloroethane (Ethylene Dichloride, EDC), must be completed and submitted to EPA as required in paragraphs (d), (e), and (f) of this section.

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Information must be reported on this form to the extent that it is known to or reasonably ascertainable by the respondent.

(i) Sunset provision. All requirements of this rule will terminate five years from the effective date of this rule.

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REPORTS IMPACT ANALYSIS

1,2-Dichloroethane (Ethylene Dichloride, EDC)
Reporting of Processing Information

1. LEGAL AUTHORITY

Section 8(a) of the Toxic Substances Control Act (90 Stat. 2027, 15 U.S.C. 2607(a)).

Section 9(a) of TSCA authorizes EPA to promulgate rules under which manufacturers and processors of chemical substances must submit reports that the Agency may reasonably require. Information submitted must be known to or reasonably ascertainable by the person reporting. To the extent feasible, the Administrator should not require unnecessary or duplicative reporting.

2. BACKGROUND

- a. Purpose - EDC is one of the high volume chemicals - produced domestically for feedstock uses and for a number of other miscellaneous, dispersive uses. There is evidence that EDC is toxic to humans and that it is carcinogenic in animals. EPA is concerned that widespread EDC exposure and release may present unreasonable risks to health and to the environment.

The purpose of this rule is to obtain information about the processing of EDC into products intended for dispersive uses -- those in which some or all the substance is eventually released into the environment. Such products may have widespread applications in the workplace and by consumers, and thus may present widespread exposure and release potential.

- b. Procedural Requirements - Under this rule, persons who process EDC into a mixture, article, or other product, or repackage EDC for distribution in commerce, are required to submit a one-time report of EDC usage, quantities processed per unit of product and number of product units produced annually. This information must be reported by the processor on EPA Form # _____, "Processing of 1,2-Dichloroethane (Ethylene Dichloride, EDC)".

Processors who react EDC to make other chemical substances, who process EDC for use in FIFRA-registered pesticides or as motor vehicle fuel additives, and small processors (as defined by this rule) are not subject to this rule. Persons who process EDC solely for research and development purposes, as an impurity in other substances, or who process formulated mixtures

containing EDC also are exempted from reporting under this rule.

- c. Unavailability From Other Data Sources - Agency efforts, as well as those of its contractors, have been unable to substantiate current, miscellaneous uses of EDC, partly due to the fact that such uses represent only a small percentage (although the quantity of EDC used dispersively is believed to be large) of total domestic EDC production and partly due to proprietary considerations. Distribution of EDC for miscellaneous uses appears to be highly fragmented and end use data are often considered proprietary.

3. ALTERNATIVES

- a. Voluntary Reporting - As noted above, several efforts to obtain voluntary information by contract have been unsuccessful. Basically, we have been unable to identify EDC processors. In cases where processors are known, they have been reluctant to provide the necessary information for convenience or proprietary reasons. Therefore, the only viable alternative for obtaining necessary information concerning EDC dispersive uses is to seek information directly from processors under this section 8(a) rule.
- b. Small Business Definition - Section 8(a)(3) requires that small businesses be exempted from reporting requirements unless a chemical substance or mixture is subject to a rule proposed or promulgated under TSCA section 4, 5(b)(4), or 6. No EDC rule under these sections has yet been proposed, although such actions could be proposed depending on the results of this section 8(a) rule.

This rule exempts "small processors" who employ ten or fewer full-time workers from the reporting requirements under this rule. This exemption, in conjunction with other reporting exclusions in this rule, will greatly reduce the reporting burden of this rule and yet should obtain sufficient information about the dispersive uses of EDC to meet the needs of the TSCA regulatory investigation. It is estimated that the small processor exclusion would eliminate about 40% of the potential respondents and reduce the reporting costs to industry by \$54,000, or 1800 reporting hours.

4. IMPACT ANALYSIS

- a. Work Hour Requirements/Costs - Dispersive uses of EDC are believed to represent a small percentage of total annual EDC production. Since only a small segment of industrial use of EDC will be affected by this

- 1 -

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reporting requirement, the overall reporting burden is expected to be minimal.

The Agency can only estimate the number of EDC processors subject to this rule and the resultant reporting costs. No known existing source of information identifies the number of EDC processors. This rule is designed to obtain this information.

An industry-wide survey was conducted by NIOSH some time ago to identify chemical usage in the workplace. According to this survey, the use of EDC appeared to be widespread at a large number of industrial sites (projected to be approximately 148,000). For reasons discussed in the preamble to this proposed rule, EPA does not believe the number of processors who will be required to report is anywhere near the number of work sites where EDC might be used as projected in the NIOSH survey.

In order to obtain a better estimate of numbers of potential EDC processors, data from the Bureau of Census, 1977 Census of Manufactures, were analyzed. Standard Industrial Classification (SIC) Categories of Manufactures were examined to identify those SIC categories of manufactures which represent the industrial applications believed to be typical for EDC based on the NIOSH survey. On this basis, EPA estimates that EDC could potentially be used in approximately 30 Standard Industrial Classification Categories of Manufactures. Analysis of Census of Manufactures data indicates that there are approximately 10,000 plant sites (with 20 or more employees) within those categories of manufactures.

The number of plant sites at which EDC is processed to prepare products for dispersive use is expected to be much smaller than the number of industrial sites at which EDC containing products or mixtures are present. Furthermore, this rule would exclude those sites using EDC as a chemical reactant and those processing EDC for pesticidal uses or as motor vehicle fuel additives. Therefore, only a small fraction of sites where EDC is present would actually be subject to this rule. While the data needed to estimate that fraction are not available, the NIOSH survey referred to previously was able to verify the presence of EDC in only about 10% of the sites where its investigators found the types of products being used that were considered in our analysis of the Census of Manufacturers data. Therefore, we assume for this analysis that as many as 10% of 10,000 sites (1000 sites) may potentially be subject to reporting requirements under this proposed rule.

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(1) Respondents

- (a) Number of Respondents - As discussed above we have estimated that as many as 1000 plant sites may be subject to reporting under this proposed rule. However, the fact that EPA and its contractors have been unable to discover the extent of the dispersive uses of EDC may reflect a significant decline in processing for these uses and indicate that the actual number of respondents that would have to report under this rule could be fewer than 1000.
- (b) Frequency of Report - The section 8(a) information on dispersive uses of EDC will be gathered on a one-time basis.
- (c) Work Hour Requirements and Costs - We estimate that each subject plant site will submit one report. An estimated maximum total of 1,000 reports are to be submitted under this section 8(a) rule, requiring 4.5 hours/form (for a total of 4500 hrs.) to complete at an estimated cost to industry of \$135/form (or a total of \$135,000).

Work-hour reporting estimates are based primarily on the cost analyses for the asbestos Secondary Processor Reporting Form (EPA Form 7710-37). These estimates were used for comparison because of the similarity in scope and data elements to be reported on both forms. Part II (company information) of the EDC reporting form is quite similar to Part I of the asbestos secondary form, and it is estimated to require one-half hour to complete. The balance of the EDC form is estimated to require four hours to complete, based on the data required, including one-half hour of legal scrutiny. Thus, the EDC Reporting Form is estimated to take a total of four and one-half hours to complete. The one-half hour difference in total completion times between the EDC and asbestos forms is due to a slight increase in number of data elements to be reported on the EDC form.

A weighted-average cost of \$30 per hour for all personnel was used to calculate the overall costs of each section of the EDC Reporting Form. The reasons for this choice are:

- (1) Clerical hours could not be separated from technical staff hours required to complete each section. Clerical time costs are estimated to be \$10 per hour, while technical time costs are estimated to be \$30 per hour.

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- (2) Some legal and upper management time (costing more than \$50 per hour) should also be required. The amount of clerical time at less than \$30 per hour and legal and upper management at more than \$30 per hour are assumed to combine with technical staff time to give a weighted average of \$30 per hour.

The underlying rationale for determining reporting costs was presented in a report to the Agency, prepared by Arthur Young and Company entitled, "Economic Impact Analysis for the TSCA Section 8(a) Rule, Reporting Commercial and Industrial Uses of Asbestos".

The following is a tabulated estimate of costs to industry and to the Agency for completing the one-page "Processing of EDC" reporting form:

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ESTIMATED REPORTING COSTS
PROCESSING OF EDC
PROPOSED SECTION 8(a) INFORMATION GATHERING RULE

I. Industry Costs

a.	Maximum number of respondents	1000
b.	Frequency of report*	1
c.	Work hours required for each respondent to collect data and complete a one-time reporting form:	
	Part I	**
	Part II	1/2 hr.
	Part III	1/2 hr.
	Part IV	3 hrs.
	Legal Review	1 1/2 hr.
	Total	<u>4 1/2 hrs.</u>
d.	Cost at estimated \$30/hr.***. x 4 1/2 hrs.	\$135/form
e.	Total cost (Cost/form x Est. respondents)	<u>\$135,000</u>

II. Agency (EPA) Costs

a.	Work-hours to process each form (compile, document control, distribute, etc.)	3
b.	Est. labor costs/hr.	\$15.00
c.	Other associated costs (ADP, etc.)	5.00
d.	Total cost/form processed	50.00
e.	Total costs (1000 respondents) x (\$50.00/form)	\$50,000

*Respondents must submit a one-time report of EDC usage.

**Estimate included in legal review.

***Est. Clerical = \$10/hr.
Technical = 30/hr. Estimated Average Cost = \$30/hr.
Legal = 50/hr.

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(2) Agency (EPA) Impacts

Implementation of the §8(a) rule will require the following Agency resources:

- (a) Receipt of Data, Editing, and Processing - The Management Support Division (MSD) will be responsible for receiving and processing the reporting forms. The total anticipated number of forms returned by respondents is expected to be small.
- (b) Evaluation - The Chemical Control Division has estimated _____ person/year will be required to evaluate the data generated by this rule.
- (c) Enforcement - The Office of Enforcement intends to actively enforce this rule.

(b) Secondary Impacts

- (1) Recordkeeping Changes -- Since this rule does not contain a recordkeeping requirement, there should be no changes in either Agency or respondent recordkeeping practices.
- (2) Effects on Agency Program Operations -- The Agency has sufficient resources budgeted to implement this rule.

5. RESPONDENT COORDINATION

No respondent coordination has been done since we do not know the identity of EDC processors. EPA and CPSC contractors were unable to identify such processors. Usual sources of coordination, such as with trade associations, were unavailable for EDC processors. Unlike some industries which are represented almost entirely by one or two trade associations, there is no comparable association for EDC processors. This is due to the fact that EDC processors are scattered throughout a number of diverse industries. We expect to identify some of the respondents since they will comment on the proposed rule.

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REPORTING PROCESSING OF
1,2-DICHLOROETHANE (ETHYLENE DICHLORIDE, EDC)

INSTRUCTIONS

GENERAL:

Use a separate form for each product you process and for each plant site where you process EDC. Different formulations of the same product are considered to be different products for purposes of this rule.

CONFIDENTIALITY CLAIMS:

Any information submitted may be claimed confidential in accordance with the following instructions. To assert a claim for information in this form, you must check the appropriate closed box for each item claimed as confidential and sign the Certification Statement in Part I. The Agency understands that checking company or product name is actually a claim for the link between these items and EDC. For information which may be submitted in attachments to the form, provide a copy which clearly indicates (e.g., by circling, bracketing, etc.) the information you wish to claim confidential.

In certifying this form, the person in Part I attests to the truth of the following four statements concerning all information which is claimed confidential:

1. My company has taken measures to protect the confidentiality of the information, and it intends to continue to take such measures.
2. The information is not, and has not been, reasonably obtainable without our consent by other persons, (other than government bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding).
3. The information is not publicly available elsewhere.
4. Disclosure of the information would cause substantial harm to our competitive position.

Part I -- Certification Statement

Self-Explanatory. This statement must be signed whether or not you claim information as confidential.

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Part II -- Company Information

- Enter the name and plant site address of your company.
- Enter the unique Dun & Bradstreet number for the plant site that is reported here. If you do not know the Dun & Bradstreet number for the plant site, leave this block blank.
- Enter the name and telephone number of the principal technical contact who is either responsible for completing this form, or has sufficient knowledge of its contents to respond to any questions posed by EPA concerning your report.

Part III -- Processing Information

EDC Function

- The purpose of this section is to characterize the use of EDC in your process and product(s). Several functions are listed. You may check more than one, if applicable. If you do not find an appropriate function already listed, check "other" and give a word or phrase that characterizes the function that EDC serves in your product.

Product Type

- The purpose of this question is to obtain information about the potential for human exposure to, or release to the environment of, the EDC in your product during its anticipated use and disposal.

The product types are described below:

- "Chemical Substance" means all physical forms of EDC (1,2-dichloroethane, ethylene dichloride), and includes all commercially available grades. This product type should be checked only by repackagers of EDC for distribution in commerce.

"Mixture" means a mixture containing EDC that the user will directly contact, e.g., cleaners, paints, inks, solvents, etc. This includes mixtures in containers or other articles whose purpose is to release EDC (e.g., cans of spray paint, ink pens, and other applicators).

"Articles With No Release" are articles constructed in a way to prevent human exposure or release to the environment of EDC during normal use and storage, e.g., chemical coatings on internal components and chemicals inside sealed articles as in thermometers and batteries.

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"Articles With Some Release" are articles whose material components are made of chemicals which come in direct contact with persons using the article, the atmosphere, land or water, i.e., exposure can come from leaching, evaporation, or surface contact. This includes such articles as plastic containers, chemically treated textiles, printed paper, coated appliances, etc. If EDC itself is sold in a bottle or other container it should be reported under "Mixture", not as an article. Only the container itself is an article for purposes of this form, and the substance it contains is not a component of it. Different formulations of the same product are considered to be different products for purposes of this rule.

Users

The purpose of this question is to obtain a characterization of the persons who are the major users of your product. If your product is intended for use by individuals for household, recreational, or other personal purposes, check "consumer". If your product is intended for use by industry or institutions, check "industrial". If both, check "both".

Product Identity

Enter the trade name (or names) under which you sell your product and a brief description of the kind of product it is, such as wood finish remover, textile finish, cleaning compound, etc.

Part IV -- Quantity Information

1. Reporting Year

If you processed EDC during the calendar year 1980, report for 1980 and check the 1980 box. If you are a batch processor, report for the most recent year (i.e., 1978 or 1979) in which you processed EDC and check the appropriate box.

2. Total Amount of EDC Obtained/Year

Enter the amount of EDC obtained (in metric weight units) for the reporting year.

3. Amount of Product Processed

o Number of Units: Enter the number of units of each size for the product you produced in the reporting year.

o Unit Size: Enter each unit size for the product. For example, if you produce one product in a 3-ounce size, a 5-gallon size, and a 55-gallon size, enter each product size on a separate line.

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Description of Product Unit: Enter a word or phrase
that best describes your product unit. For example, a
tube, can, bottle, bolt of cloth, drum, etc.

4. Weight of EDC per Product Unit

For each unit, give the amount of EDC (in metric weight units)
per unit; for example, 5 mg. EDC/3-oz. tube.

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Part I -- Certification Statement

I hereby certify that to the best of my knowledge and belief (1) all information reported on this form is complete and accurate, and (2) the confidentiality statements on the back of this form are true as to that information for which I have asserted a confidentiality claim. I agree to permit access to, and copying of, records by a duly authorized representative of the EPA Administrator, in accordance with the Toxic Substances Control Act, to document any information reported here.

SIGNATURE

DATE

NAME/TITLE (Type or Print)

Part II -- Company Information

1. Company Name:	4. Technical Contact:
2. Plant Site Address:	5. Telephone:
3. Dun & Bradstreet # (For Plant Site):	6. Standard Industrial Code No. (SIC):

Part III -- Processing Information

1. EDC Function	2. Product
☐ Adhesion Promoter ☐ Antistaining Agent ☐ Beneficiating Agent ☐ Binder ☐ Blending Agent ☐ Carrier ☐ Curing Agent ☐ Degreaser ☐ Descaling Agent ☐ Diluent ☐ Dispersion Agent ☐ Drier ☐ Emulsifier ☐ Finishing Agent ☐ Flotation Agent ☐ Greaseproofing Agent ☐ Latex Compounding Agent ☐ Lubricating Agent ☐ Paint & Varnish Remover ☐ Penetrant ☐ Plastics Additive ☐ Prespotting Agent ☐ Rust Remover ☐ Scouring Agent ☐ Soil Release Agent ☐ Soil Retardant ☐ Solvent ☐ Textile Specialties ☐ Water Repellent	(a) Product Type ☐ Chemical Substance ☐ Mixture ☐ Article w/some release ☐ Article w/no release (b) Users ☐ Industrial ☐ Consumer ☐ Both (c) Product Identity: _____ _____ _____
☐ OTHER (Specify) _____	

Part IV -- Quantity Information

1. Reporting Year: 1980 [], 1979 [], 1978 []		
2. Total Amount (by weight) EDC Obtained/Year	3. Amount of Product Processed	4. Weight of EDC/Product Unit
☐	☐ Units ☐ Unit Size ☐ Description of Product Unit	☐ EDC/Product Unit
		/.....
		/.....
		/.....

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FOR DISCUSSION AND REVIEW ONLY
NOT FOR RELEASE

ANNUAL REPORT TO SPAC ON ETHYLENE DICHLORIDE

FOR DISTRIBUTION BY CMA
REF. No. EDC-18

1.0 Charter

The Program Panel will appraise and evaluate the adequacy of knowledge relating to ethylene dichloride (EDC). The Panel will recommend and sponsor research in order to ascertain conditions necessary to assure the safety of workers involved in the production, handling and use of EDC and the safety of communities where such plants are located.

The EDC Panel will represent the interests of its members before Federal and State agencies in all matters relating to safety and health issues arising out of production distribution and use of EDC.

The Panel will function as a special committee under CMA bylaws, and as such will be subject to the Special Program Guidelines.

2.0 Uses

Approximately 80 per cent of the annual production of EDC is used for the synthesis of vinyl chloride. EDC also finds application as a constituent in lead-containing antiknock additives for gasoline, in fumigant-insecticide

? 2213

formulations, and as a component of metal degreasing mixtures. It is used as an intermediate in the synthesis of the ? chlorinated solvents, 1,1,1-trichloroethane, trichloroethylene, and perchloroethylene, and as a constituent of rubber cement and acrylic-type adhesives. *excess ?*

3.0 Background and Objectives

In December, 1974, representatives of thirteen producers and users of EDC requested CMA to administer a research program to increase the toxicological data base for EDC. The scope of the program was to include at least: a literature survey and interpretation, mutagenic and teratogenic studies, and chronic inhalation studies. The Research Program on Ethylene Dichloride was approved on February 24, 1975.

*Heard's
Researching*

The Panel initiated a chronic inhalation study, a metabolic study, and a teratogenic study in experimental animals. The chronic inhalation study was completed, although the final report is not satisfactory to the Panel. The researchers have been requested to provide additional information to clarify several issues in the report and the Panel is still awaiting a satisfactory response. The metabolic research had to be terminated because the Panel was unable to provide compounds which were necessary for continuation of the research. The teratogenic study was satisfactorily completed.

The Panel decided not to initiate th mutagenic testing since EDC was shown to be weakly mutagenic in the Ames test. In addition, there did not appear to be the need for the literature search.

In July 1980, the Panel voted by ballot to disband itself since no further activities were identified as necessary. However, by November of that year, the Panel reversed its decision to disband, principally because it was learned that EPA was formulating a proposed rule under TSCA Section 8(a). The Panel subsequently revised its charter to pursue an advocacy program.

4.0 Membership

See Attachment A.

5.0 Research Programs

a. Completed and Ongoing Studies (See Attachment B)

A. EDC 1.0-LT/Ihl/MS

While developing the research program for EDC, the Panel learned that a consortium of European chemical manufacturers under the leadership of Montedison, intended to have Dr. Maltoni conduct a long-term inhalation study on EDC. The

Panel d cided to participate in the European study under CMA auspices.

In January 1976, an agreement was executed with Montedison to administer a research project which would investigate the potential toxicological effects and pharmacodynamics of inhaled ethylene dichloride in laboratory animals. Professor Maltoni and Dr. Spreafico were the subcontractors to the agreement.

Full name

The following studies were included in the project:

1. Experimental investigations on the effects of EDC by inhalation on Sprague-Dawley rats.
2. Experimental investigation on the effects of EDC by inhalation on Swiss mice.

Originally the animals were to be treated for 12 months and observed until death. The treatment period was later expanded to 18 months. A final report on the long-term effects on rats and mice from inhaled EDC was sent to the Panel in May 1979.

*whose report?
Maltoni's?*

On October 18, 1979, CMA wrote to Montedison indicating that the Panel had numerous questions relating to the final report by Drs. Spreafico and Maltoni. Dr. Maltoni decided to answer these questions through his presentation at a November

1979 Cold Spring Harbor Symposium and its subsequent publications. The proceedings from the meeting were not published until 1980 and in addition, did not answer all the questions raised by CMA in the October 1979 letter. Montedison wrote to CMA in March 1981, indicating that Maltoni's presentation at Cold Spring Harbor and the subsequent proceedings did not answer all CMA's questions and submitted a detailed report by Maltoni addressing most of the Panel's questions. In July 1981, CMA wrote back to Montedison indicating that an adequate response was still not received and supplemental information was needed before final payment would be made. To date, a response has not been received.

In July 1980, CMA sent the final report submitted by Maltoni to selected government agencies indicating that many points relating to the research were still unresolved.

Additional research on the chronic effects of EDC has been conducted by the National Cancer Institute (NCI). In September 1980, NCI released a carcinogenesis bioassay which found that orally administered EDC was carcinogenic in rats and mice. Male rats exposed developed forestomach cancers, hemangiosarcomas of multiple organs, and subcutaneous fibromas. Mammary cancers were found in female ~~rats~~ rats exposed to EDC. The chemical also caused breast cancer as well as uterine cancers in female mice and respiratory tract cancers in both male and female mice.

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In September, 1979, the Panel approved funds for an on-site review of both the CMA sponsored research and the then recently released NCI sponsored gavage study. Because of recalcitrance on the part of the Italian investigator, these reviews could not take place.

EDC 2.0

An agreement was executed in October 1977 between CMA and "Mario Negri" to conduct metabolic studies on EDC. In the first phase of the study, Sprague-Dawley rats were administered EDC intravenously and orally to evaluate its metabolic fate. Following this phase, the study was to be repeated by the inhalation route.

This agreement was terminated in July 1979 and the metabolic study cancelled because of the unavailability of the six cysteine compounds which were necessary to continue the research. CMA disbursed \$30,000 towards the metabolic study out of \$60,000 which was originally committed.

A report was sent to CMA in July 1978 describing the work already completed on the distribution and metabolism of EDC in laboratory animals. This report was sent to the appropriate government agencies.

EDC 3.0-Ter-Ihl

In the Fall of 1977, CMA contracted with Dow Chemical Company to conduct a teratologic study on the effects of maternally inhaled EDC on rat and rabbit embryonal and fetal development. The final report was received by CMA in April 1979 and submitted to the appropriate government agencies in March 1980.

EDC 4.0-Rep-Ihl

In the Fall of 1977, an agreement was signed with Dow Chemical Company to conduct a single generation reproduction study on inhaled EDC in rats. The protocol for this study was revised and signed by Dow in February 1979. The final report was submitted to CMA in January 1980 and released to the appropriate government agencies in May 1980.

b. Future Studies

None Planned

c. Ongoing Monitoring by Task Groupos

None

d. Auditing

None.

e. Complimentary Research Programs

None.

6.0 Advocacy

a. Existing Regulations/Recommendations

The current Federal standard for ethylene dichloride is 50 parts of ethylene dichloride per million parts of air (ppm) averaged over an eight-hour work shift, with a ceiling level of 100 ppm and a maximum acceptable peak of 200 ppm for 5 minutes in any three-hour period. NIOSH has recommended that the permissible exposure limit be reduced to 5 ppm averaged over a work shift of 10 hours per day, 40 hours per week, with a ceiling level of 15 ppm averaged over a 15-minute period.

ACGIH TWA: 10ppm (40mg/m³)

STEL: 15ppm (60mg/m³)

b. Proposed and Anticipated Regulations

The Panel received a TSCA Section 8(a) draft proposed rule from EPA.

This rule would require certain processors of EDC to identify themselves and to report the intended uses of the EDC-containing products they make. These processors would also report quantities of EDC obtained and used for each of their processes or products.

EPA wishes to evaluate whether dispersive uses of EDC pose an unreasonable risk to health or the environment. Information reported under this rule will be considered by EPA in assessing potential risks and determining whether regulation of certain dispersive uses of EDC is needed.

As of September 1981, EPA has not taken any action with regard to the draft proposed rule.

CMA has learned that EPA's Environmental Criteria and Assessment Office is updating their health assessment document on EDC. The document compiled will be used to determine whether EDC should be regulated as a hazardous air pollutant. These health assessment documents are also used by other offices within EPA for making regulatory decisions.

7.0 Key Issues

None

8.0 Liaison with Other Associations and Interest Groups

None

9.0 Controversial Issues

None

10.0 Critical Dates

None

11.0 Future Needs

None

12.0 Financial Status

See Attachment C

13.0 Summary

The EDC Program Panel has undertaken four research projects:

1. The chronic inhalation study in rats and mice was completed. However, two questions still remain unanswered by the researchers.

2. The metabolic study in rats was terminated in mid-stream because of the unavailability of six cysteine compounds which were necessary to continue the research. A report describing the work completed was submitted to appropriate government agencies.

3. The teratology study on the effects of maternally inhaled EDC on rat and rabbit embryonal and fetal development was completed and the final report was submitted to appropriate government agencies.

4. The single generation reproductive study on inhaled EDC in rats was completed and the final report was submitted to appropriate government agencies.

No additional research is planned. However, the Program Panel recently added an advocacy amendment to its charter and may be pursuing an advocacy program.

ETHYLENE DICHLORIDE SPECIAL PROGRAM FINANCIAL STATEMENT
 Period Ending - August 31, 1981
 Phase I and II - 14 Companies

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Amount Invoiced: \$384,964
 Amount Received: \$384,964
 Budget Authorized: \$439,552¹

<u>Service/Program Category</u>	<u>Budget Authorized</u>	<u>Actual Commitment</u>	<u>Disbursement</u>	<u>Unpaid Balance</u>	<u>Authorized Funds Available</u>
<u>Research</u>					
EDC 1.0-TOX-Ihl-MA/SP	\$137,500	\$137,500	\$118,350	\$ 19,150	\$ -0-
EDC 2.0-MET-Intra/Ori/SP	30,000	30,000	30,000	-0-	-0-
EDC 3.0-TER-Ihl-Dow	28,000	28,000	28,000	-0-	-0-
EDC 4.0-REP-Ihl-Dow	92,600	29,600	92,600	-0-	-0-
<u>Subtotal Research</u>	<u>\$288,100</u>	<u>\$288,100</u>	<u>\$268,950</u>	<u>\$ 19,150</u>	<u>\$ -0-</u>
<u>Administration</u>	\$121,452 ²	\$121,452			
Direct Charges (8/31/81)			\$ 62,200		
Travel Charges			1,274		
Miscellaneous			976		
<u>Subtotal Administration</u>	<u>\$121,452</u>	<u>\$121,452</u>	<u>\$ 64,450</u>	<u>\$ 57,002</u>	<u>\$ -0-</u>
<u>Contingency</u>	\$ 30,000 ³	\$ -0-	\$ -0-	\$ 30,000	\$ -0-
 <u>TOTAL</u>	 <u>\$439,552</u>	 <u>\$439,552</u>	 <u>\$333,400</u>	 <u>\$106,152</u>	 <u>\$ -0-</u>

1. \$54,588 has not been invoiced.

2. Difference between total amount committed to program and total amount committed to research.

3. \$30,000 paid to MET, \$30,000 transferred to contingency.

ETHYLENE DICHLORIDE

<u>Report Title and Contract Number</u>	<u>Contractor</u>	<u>Contract Execution Date</u>	<u>Present Level of Funding</u>	<u>Comments</u>
Studies on Long-term Effects on Rats and Mice of Ethylene Dichloride, Administered by Inhalation (18 months) (EDC 1.0-LT/Ihl/M.S.)	Montedison, S.p.A.	Jan. 16, 76	\$137,500	Released July 11, 80
Distribution and Metabolism of 1,2 Dichloroethane (EDC) in Experimental Animals (EDC 2.0)	Mario Negri	Oct. 6, 77	30,000	Terminated. Interim report released June 25, 80
The Effect of Inhaled EDC on Embryonal and Fetal Development in Rats and Rabbits (EDC 3.0)	The Dow Chemical Company	Oct. 31, 77	28,000	Released March 25, 80
EDC: Single Generation Inhalation Reproduction Study in Rats (EDC 4.0)	The Dow Chemical Company	Oct. 31, 77	92,600	Released May 30, 80

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BIOMEDICAL AND ENVIRONMENTAL
SPECIAL PROGRAMS ADVISORY COMMITTEE

William C. Becker
Vice President
Employee Relations and
Public Affairs
The BFGoodrich Company
Chemical Group
6100 Oak Tree Boulevard
Cleveland, Ohio 44131
(216) 524-0200

Calvin J. Benning, Ph.D.
Director, Regulatory Affairs
Essex Chemical Corporation
1401 Broad Street
Clifton, New Jersey 07015
(201) 773-6300

H. Donald Feeney
Vice President
External Affairs
Borg-Warner Chemical Corporation
International Center
Parkersburg, West Virginia 26101
(304) 424-5414

Conrad Kent, Esquire
Vice President-Law
Stauffer Chemical Company
Westport, Connecticut 06880
(203) 222-4369

George J. Levinskas, Ph.D.
Director, Environmental Assessment
and Toxicology
Monsanto Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63166
(314) 694-8809

Myrl E. Miller, Ph.D.
Occupational Health
Consultant
IMC Chemical Group
421 East Hawley Street
Mundelein, Illinois 60060
(312) 566-2600

Noble Robinson
Director of Environmental
Affairs
Mallinckrodt, Inc.
P.O. Box 5840
St. Louis, Missouri 63134
(314) 895-2703

Curtis W. Smith, Ph.D.
Senior Consultant
Health, Safety and Environment
Shell Chemical Company
P.O. Box 2463
Houston, Texas 77001
(713) 241-0578

Jerry M. Smith
Director of Toxicology
Rohm and Haas Company
Spring House, Pennsylvania 19477
(215) 641-7536

Otto Sturzenegger, Ph.D., Chairman
Chairman of the Board and Chief
Executive Officer
CIBA-GEIGY Corporation
Ardsley, New York 10502
(914) 478-3131

Gary Sunshine
General Manager
Health and Environmental Affairs
ICI Americas
Wilmington, Delaware 19897
(302) 575-4516

Gary Ter Haar, Ph.D.
Director, Toxicology and Industrial
Hygiene Department
Ethyl Corporation
451 Florida Avenue
Baton Rouge, Louisiana 70801
(504) 388-7853

Carl Umland
Environmental Health Coordinator
Exxon Chemical Americas
P.O. Box 3272
Houston, Texas 77001
(713) 870-6762

Joan E. Young
Product Registration Specialist
Petrolium-Tretolite Division
369 Marshall Avenue
St. Louis, Missouri 63119
(314) 961-3500

John J. Zimmerman (Jeff)
Manager, Regulatory and Legislative
Affairs
ARCO Chemical Company
3801 West Chester Pike
Newtown Square, Pennsylvania 19073
(215) 359-2202

Ex-Officio Members

Robert Neal, Ph.D.
President
Chemical Industry Institute of
Toxicology
P.O. Box 12137
Research Triangle Park,
North Carolina 27709
(919) 541-2070

Thomas W. Mooney
Manager, Technical-Government
Relations
The Proctor & Gamble Company
Ivorydale Technical Center
Room 2N54
Spring Grove & June Streets
Cincinnati, Ohio 45217
(513) 763-5187

CMA Ex-Officio Members

Geraldine V. Cox, Ph.D.
Vice President, Technical Director
Chemical Manufacturers Association
2501 M Street, N.W.
Washington, D.C. 20037
(202) 887-1260

Edmund B. Frost, Esquire
Vice President-General Counsel
Chemical Manufacturers Association
2501 M Street, N.W.
Washington, D. C. 20037
(202) 887-1350

Hasmukh C. Shah, Ph.D., Staff Executive
Director, Special Programs
Chemical Manufacturers Association
2501 M Street, N.W.
Washington, D.C. 20037
(202) 887-1192

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