Fiche: A01
Paper: A06
PB88-231543
May 31, 1988
540/RS-88-020

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing FORMALDEHYDE AND PARAFORMALDEHYDE as the Active Ingredient

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

FORMALDEHYDE AND PARAFORMALDEHYDE

AS THE ACTIVE INGREDIENT

CASE NUMBER 556

EPA/OPP PESTICIDE CHEMICAL CODES 043001 and 043002

CAS REGISTRY NUMBERS 50-00-0 AND 30525-89-4

MAY 17, 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

TABLE OF CONTENTS

I. Introduction 1

II. Chemical(s) Covered by this Standard 4
- A. Description of Chemical
- B. Use Profile

III. Agency Assessment 7
- A. Summary
- B. Preliminary Risk Assessment
- C. Other Science Findings
- D. Tolerance Reassessment

IV. Regulatory Position and Rationale. 21
- A. Regulatory Positions
- B. Criteria for Registration
- C. Acceptable Ranges and Limits
- D. Required Labeling

V. Products Subject to this Standard 34

VI. Requirement for Submission of Generic Data 36
- A. What are generic data?
- B. Who must submit generic data?
- C. What generic data must be submitted?
- D. How to comply with DCI requirements
- E. Procedures for requesting a change in protocol
- F. Procedures for requesting extensions of time
- G. Existing stocks provisions upon suspension or cancellation

VII. Requirement for Submission of Product-Specific Data . .43

VIII. Requirement for Submission of Revised Labeling 44

IX. Instructions for Submission. 45
- A. Manufacturing use products (sole active)
- B. Manufacturing use products (multiple active)
- C. End use products
- D. Intrastate products
- E. Addresses

APPENDICES

I. DATA APPENDICES

Guide to Tables 48

Table A 50

Table B 73

II. LABELING APPENDICES

Summary of label requirements and table 77

40 CFR 162.10 Labeling Requirements 85

Physical/Chemical Hazards Labeling Statements 94

Storage Instructions 95

Pesticide Disposal Instructions 96

Container Disposal Instructions 97

III. BIBLIOGRAPHY APPENDICES

Guide to Bibliography 98

Bibliography 100

IV. FORMS APPENDICES

EPA Form 8580-1 FIFRA §3(c)(2)(B) Summary Sheet 107

EPA Form 8580-6 Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data 108

EPA Form 8580-4 Product Specific Data Report (End-Use Products) 109

EPA Form 8570-27 Generic Data Exemption Statement 111

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration system in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

OES	Office of Endangered Species, U.S. Fish and Wildlife Service
OTS	Office of Toxic Substances
PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

1. Studies that are acceptable to satisfy the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this

---

[1]The scientific reviews may be purchased from the National Technical Information Service, ATTN: Order Desk, 5285 Port Royal Road, Springfield, Virginia 22161. Orders may be placed by telephone to National Technical Information Service at (703) 487-4650.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the ingredient and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of a product to reduce the levels of impurities or contaminants;

4. Restriction of the use of a product to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about these pesticides. These data are listed in the Tables A, B, and in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the

Agency of any information, including interim or preliminary results of studies, if that information suggest possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as a product is registered under FIFRA.

II. CHEMICAL(S) COVERED BY THIS STANDARD

A. Description of chemical(s)

The following chemical(s) are covered by this Registration Standard:

Chemical Name:	Formaldehyde	Paraformaldehyde
Common Name	Formic aldehyde, Methanal, Oxomethane, Oxymethylene, Methylene oxide, Formalin	Polyoxymethylene, Mixed polyoxy-methylene glycols
CAS Registry Number	50-00-0	30525-89-4
EPA/OPP Pesticide Chemical Code	043001	043002
Empirical Formula	CH_2O	$HO(CH_2O)_xH$

Description of Physical Characteristics of Chemical

Color	Colorless	Colorless
Physical State	Gas	Crystalline, Pelleted/Tableted Wettable Powder/Dust
Odor	Pungent	Pungent
Melting Point	NA(gas at room temp.)	64°C
Boiling Point	-19.5°C(-3°F)	NA(tech. is solid at room temp.)

Description of Physical Characteristics (Cont'd)

	Formaldehyde	Paraformaldehyde
Solubility	Very soluble in water - up to 55%, soluble in ether, alcohol	Dissolves slowly in cold water, more rapidly in hot water, hydrolyzing and depolymerizing as it dissolves
Vapor Pressure	Unavailable	Unavailable
Molecular Weight	30.03	Variable; avg. = 600
Octanol/Water Partition Coefficient	0.1348	
Corrosion Characteristics	Corrosive to metal	

B. Use Profile

Type of Pesticide	Disinfectant, Fungicide, Microbiocide, Preservative of pesticidal formulations	Disinfectant, Fungicide, Microbiocide, Preservative of pesticidal formulations
Pests Controlled	Bacteria, Fungi, Viruses, Algae	Bacteria, Fungi,

Use Profile (Cont'd)

	Formaldehyde	Paraformaldehyde
Registered Sites	Food and non-food crops, farm/animal premises, oil recovery systems, industrial preservatives, medical premises & equipment, industrial, institutional premises, contents & equipment, household, preservative of pesticidal formulation	Sugar maple tree tapholes, oil recovery systems, lockers, locker rooms, hatchery equipment, hatcheries, industrial preservatives and additives, preservative of pesticidal formulation
Predominant Use(s)	Surface disinfectant, industrial biocide hatcheries, preservative of pesticidal formulations	Preservation of oil well drilling muds, mildew and odor control on commercial premises
Formulation Types Registered	Gas, pelleted/tableted, soluble concentrate/ liquid, flowable concentrate; 37%, 44% & 45% formulation intermediates (manufacturing use products)	Pelleted, tableted wettable powder/ dust, crystalline
Method(s) of Application	Spray or Dip, Wipe, Soak, Manual Pour, Fumigation, Automatic Metering Devices	Manual Insert, Jet Mixer, Generator, Fumigation

III. AGENCY ASSESSMENT

A. INTRODUCTION

This registration standard covers formaldehyde and paraformaldehyde, a solid polymer of formaldehyde. Paraformaldehyde is covered by this standard because it hydrolyzes to form formaldehyde in an aqueous solution or depolymerizes to form formaldehyde gas when exposed to air.

This standard covers products containing formaldehyde or paraformaldehyde currently classified as either active or inert ingredients. As inert ingredients, formaldehyde and paraformaldehyde are intentionally added to preserve the pesticidal activity of formulations by preventing deterioration caused by bacteria and fungi. As preservatives in formulations, formaldehyde or paraformaldehyde perform a pesticidal function. Therefore, the Agency has determined that formaldehyde and paraformaldehyde should be categorized as active ingredients in all products in which they are used, including those in which they currently are only intentionally added as an inert ingredient. Thus, all products containing formaldehyde and paraformaldehyde as a preservative of the formulation will be considered to contain these chemicals as active ingredients.

B. REGULATORY HISTORY

Less than 1% of the total amount of formaldehyde produced annually is used for pesticidal purposes. The first pesticidal uses were registered in 1948 for formaldehyde and in 1953 for paraformaldehyde. Formaldehyde is also one of the 55 toxic inerts the Agency has identified for priority consideration. Formaldehyde was assigned to this priority group on the basis of positive carcinogenicity and mutagenicity evidence.

In 1979, interim results from a Chemical Industry Institute of Toxicology (CIIT) study indicated that formaldehyde produced nasal tumors in rats. In November 1980, the Federal Panel on Formaldehyde, formed by several Federal agencies under the sponsorship of the National Toxicology Program, published a report concluding that "formaldehyde should be presumed to pose a risk of cancer to humans".

Initially, the Agency focused its investigation of formaldehyde on the uses covered under the Toxics Substances Control Act (TSCA). In February 1982, the Agency decided that although formaldehyde had been found to be carcinogenic in the CIIT study (completed in 1981), the available information concerning its cancer risk to humans did not meet the statutory criteria ("...presents or will present a significant risk of serious

or widespread harm to human beings from cancer...") for priority designation under section 4(f) of TSCA. In October 1983, the Agency funded the National Center for Toxicological Research to sponsor a Consensus Workshop on Formaldehyde to further assist in its evaluation of formaldehyde. In November 1983, the Agency rescinded its February 1982 decision and asked for public comment to determine whether formaldehyde should be given priority consideration under section 4(f) of TSCA. In May 1984, the Agency announced that two formaldehyde exposure categories, the manufacture of apparel from fabrics treated with formaldehyde and residential exposure from formaldehyde based resins, triggered section 4(f) of TSCA.

The Agency referred its investigation of risk to garment workers from fabrics treated with formaldehyde to the Occupational Safety and Health Administration (OSHA) in February, 1986 because of OSHA's jurisdiction in that area and its proposed revision of the workplace exposure levels for formaldehyde (50 FR 50412). On December 4, 1987, OSHA issued its revised occupational safety and health standard for occupational exposure to formaldehyde (29 CFR 1910.1048). This standard announced the reduction of the permissible exposure limit from 3 parts formaldehyde per million parts of air to 1 part formaldehyde per million parts of air measured as an 8-hour time-weighted average.

The Agency's Office of Toxic Substances (OTS) performed a risk assessment for residential exposure triggering section 4(f) concerns. This document entitled "Assessment of Health Risks to Garment Workers and Certain Home Residents from Exposure to Formaldehyde" was released on April 16, 1987. This assessment of human health risks associated with formaldehyde states the Agency's position that formaldehyde should be classified as a group [B1] probable human carcinogen in accordance with the Cancer Risk Assessment Guidelines. The hazard identification and cancer potency estimations in this risk assessment are used in this registration standard.

C. SUMMARY

The Agency reviewed data submitted to support the registration of formaldehyde and paraformaldehyde, as well as published reports. Based on the available data, the Agency has reached the following conclusions.

1. Formaldehyde has been found to be carcinogenic in animal studies and there is limited evidence of carcinogenicity in humans. The Agency has classified formaldehyde as a Group [B1] Probable Human Carcinogen.

2. Based on available exposure data, the Agency has estimated the worst-case risks to agricultural workers from use of formaldehyde as a preservative in a pesticide formulation to be less than 1.2×10^{-6} [B1] (see Section III.D). Estimates of the dietary risk and risk to workers from non-agricultural uses have not been calculated because necessary data are not yet available.

3. An acceptable daily intake (ADI) has not been established for formaldehyde. When requested toxicological data are received, an ADI will be established. Based on requested residue data, a tolerance reassessment will be performed.

4. At this time, the Agency is unable to assess risks to endangered species because necessary data are not available to estimate the environmental concentrations resulting from certain uses (see Section III.E.8). The Agency is requiring that monitoring data be submitted in order to assess the risk to endangered species.

D. PRELIMINARY RISK ASSESSMENT

Use of formaldehyde and paraformaldehyde may result in worker exposure, both agricultural and non-agricultural, and dietary exposure. Non-agricultural uses account for the largest percentage of formaldehyde and paraformaldehyde used for pesticidal applications. The use of formaldehyde and paraformaldehyde for the preservation of drilling muds and production fluids in secondary oil recovery systems may result in non-agricultural worker exposure. Formaldehyde's use for the preservation of metalworking fluids and biological tissues, and its use in sanitization and disinfection of non-food surfaces, instruments and equipment may also result in non-agricultural worker exposure. Formaldehyde's use as a preservative in products registered for use in indoor/outdoor bait applications and toilet bowls/urinals may result in non-agricultural worker exposure. Paraformaldehyde's use for mold, mildew and odor control in enclosed spaces may also result in non-agricultural worker exposure.

Agricultural worker exposure may result from use of formaldehyde for control of pathogenic fungi and/or bacteria on some food crops, ornamentals, soil and planting containers, and for control of fungi on garlic seed. Agricultural worker exposure may also result from formaldehyde's use as a preservative in products registered for use on tree fruit and nut crops, vegetable crops, small fruits, field crops, cereal grain crops, ornamentals, rangeland, golf courses, greenhouse crops, mushroom house soil and seed treatment. Paraformaldehyde's use as a preservative in products registered for use on tree fruit and nut crops, vegetable crops, small fruits, seed treatment, ornamentals and general outdoor application may also result in agricultural worker exposure. Formaldehyde's and paraformaldehyde's use for sanitization of hatching eggs may also result in agricultural worker exposure. Paraformaldehyde's use on sugar maple trees may also result in agricultural worker exposure.

Dietary exposure may result from use of formaldehyde and paraformaldehyde as a preservative in products registered for use on a variety of crops. Dietary exposure may also result from formaldehyde's use on some food crops to control pathogenic fungi and/or bacteria. Paraformaldehyde's use on sugar maple trees may result in dietary exposure. The original exemptions from tolerances were established on the assumption that significant residues of formaldehyde would not be present. The Agency is now requiring plant metabolism residue data to determine dietary exposure.

1. Risks to Agricultural Workers

The Agency has reliable data with which to estimate applicator exposure for most agricultural uses. The Agency quantified exposure for uses of formaldehyde as a preservative in a pesticide formulation applied to orange trees. This use pattern was chosen because it is known to involve one of the highest levels of exposure for agricultural application of pesticides. Specifically, the Agency estimated the exposure of a worker mixing and loading the pesticide and then making one application by boom sprayer and four applications using airblast equipment. Exposure was estimated based on a concentration of 0.3% formaldehyde in the formulation as a preservative (0.3% concentration was chosen because a review of the product labels indicated this was the highest concentration expected). Exposure estimates were calculated for a mixer/loader wearing protective gloves, long pants and a short-sleeve shirt. The maximum exposure levels estimated for the worker were 0.87 ug/kg/yr (inhalation) plus 397 ug/kg/yr (dermal) of formaldehyde.

2. Inhalation Risks

The OTS risk assessment for formaldehyde used the CIIT study for the dose-response modeling and calculated a unit risk of 1.3×10^{-5} for a daily exposure of 1 ug/m^3 over a 70 year period. These calculations have been adjusted to account for the worst-case worker exposure over a 40 year worklife as follows:

Assuming a respiratory rate of 1.74m^3/hr, a 1 ug/m^3 ambient exposure results in a daily exposure of

$$1 \text{ ug/m}^3 \times 1.74 \text{ m}^3\text{/hr} \times 24\text{hrs} = 41.76 \text{ ug/day.}$$

Assuming a bodyweight of 60kg (human female), exposure equals

$$41.76 \text{ ug/day}/60 \text{ kg} = 0.696 \text{ ug/kg/day}$$

The Q_1^* can be derived as follows:

$$\text{Risk} = \text{Daily exposure (mg/kg)} \times Q_1^*$$

$$Q_1^* = \frac{1.3 \times 10^{-5}}{0.696 \text{ mg/kg/day} \times 10^{-3}} = 1.87 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$$

The maximum exposure inhalation level of 0.87 ug/kg/yr for pesticide workers can be converted to a daily exposure of 2.4×10^{-6} mg/kg/day.

$$\text{Risk} = 2.4 \times 10^{-6} \text{ mg/kg/day} \times 1.87 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$$

$$= 4.6 \times 10^{-8}$$

Since the Q_1^* was derived from a 70 year (lifetime) exposure, this risk must be prorated for a 40 year worklife as follows:

$$4.6 \times 10^{-8} \times \frac{40}{70} = 2.6 \times 10^{-8}$$

Thus, the risk from inhalation exposure was estimated to be in the range of 10^{-7} to 10^{-8}.

3. Dermal Risks

To estimate the risk to an agricultural mixer/loader/applicator from dermal exposure, a 397 ug/kg/yr exposure over a 40 year worklife was used. This estimate assumed 100% dermal absorption. However, it appears that less than 10% of radiolabeled formaldehyde penetrates the skin after 48 hours. Of the absorbed radiolabeled formaldehyde, very little formaldehyde is expected to remain because it appears to rapidly convert to formate and carbon dioxide or to combine with tissue constituents. Therefore, exposure was adjusted for 10% dermal absorption.

Maximum expected dermal exposure = 397 ug/kg/yr.

= 1.09 ug/kg/day

Assuming 10% penetration = .109 ug/kg/day

$= 1.09 \times 10^{-4}$ mg/kg/day

$$\text{Risk} = 1.09 \times 10^{-4} \text{ mg/kg/day} \times 1.87 \times 10^{-2} \text{ (mg/kg/day)}^{-1}$$

$$= 2.0 \times 10^{-6}$$

Again, since the Q_1^* was based on a 70 year exposure, this risk must be prorated for a 40 year worklife as follows:

$$2.0 \times 10^{-6} \times \frac{40}{70} = 1.1 \times 10^{-6}$$

Thus, the risk from dermal exposure was estimated to be no greater than 10^{-6}, when a 10% dermal absorption was assumed.

3. Risks to Non-agricultural Workers

The Agency does not have data to quantify applicator exposure for the non-agricultural uses. The Agency has

developed a strategy to obtain exposure data on the uses of antimicrobial pesticides, many of which have non-agricultural uses. When these data are received, as well as indoor inhalation exposure reentry data required by this standard, they will be used to assess the risk from non-agricultural uses of formaldehyde and paraformaldehyde.

4. Dietary Risks

Data are not available to assess dietary risk from use of formaldehyde and paraformaldehyde. An assessment of the dietary risk will be made when requested residue data and toxicology data are submitted.

E. SCIENCE FINDINGS

Most of the toxicological information on formaldehyde is from published sources. These sources are analyzed in the Agency's risk assessment on formaldehyde entitled "Assessment of Health Risks to Garment Workers and Certain Home Residents from Exposure to Formaldehyde" (April, 1987). Also, the Agency evaluated data submitted in support of pesticide registrations. The toxicity of paraformaldehyde is believed to be identical to that of formaldehyde since it is known to hydrolyze or depolymerize into formaldehyde rapidly.

1. Acute Toxicity. Numerous published acute toxicity studies exist. However, the Agency does not have access to the raw data supporting these published studies. Therefore, none is adequate for FIFRA regulatory purposes. However, based on published and/or unpublished acute toxicity studies, the following toxicological characteristics of formaldehyde and paraformaldehyde are expected:

Formaldehyde

Acute oral toxicity:
Toxicity Category 3; LD_{50} = 800 mg/kg (rat)
Acute dermal toxicity:
Toxicity Category 3; LD_{50} > 2 g/kg
Acute inhalation toxicity:
Toxicity Category 3;
Lowest lethal concentration = 250 ppm (4hr exposure)
Primary eye irritation: Toxicity Category 1
Primary skin irritation: Toxicity Category 2
Major route of exposure: inhalation, dermal

Paraformaldehyde

Acute oral toxicity:
Toxicity Category 3; LD_{50} > 1.6 g/kg (rat)
Acute dermal toxicity:
Toxicity Category 3; LD_{50} > 2 g/kg

Acute inhalation toxicity:
Toxicity Category 1; LC_{50} about 14 ppm
Primary eye irritation:
Toxicity Category 1
Primary skin irritation
Toxicity Category 2
Major route of exposure: inhalation, dermal

Exposure to formaldehyde may cause irritation of the eyes and upper respiratory system. Formaldehyde is a well-known dermal sensitizer and after sensitivity is induced, further exposure can elicit allergic response. Most persons experience discomfort when exposed within the range of 0.1 to 3 ppm. Acute oral (rat), acute dermal (rabbit), acute inhalation (rat), primary eye irritation (rabbit) and dermal sensitization toxicity studies are required.

2. Subchronic Toxicity. Subchronic exposures of 2 ppm or greater have been reported to affect the mucociliary clearance system, which may increase a person's susceptibility to infections and other respiratory diseases. As with the acute toxicity studies, the data are not adequate for FIFRA regulatory purposes. A 90-day feeding study (rodent and non-rodent), 21-day dermal study (rabbit) and a 90-day inhalation study (rat) are required. A 90-day dermal study (rabbit) is reserved pending the results of the 21-day dermal study.

3. Chronic Feeding and Oncogenicity.

Classification. Based on the available data, formaldehyde is classified by the Agency as a B_1 carcinogen because there is sufficient evidence of carcinogenicity from animal studies, and limited evidence of carcinogenicity in humans.

Epidemiology. Epidemiological studies indicate formaldehyde may be a human carcinogen, though the evidence is classified as limited because exposures to multiple chemicals may confound the findings of excess cancers.

Twenty-eight epidemiological studies are reviewed in the OTS risk assessment. Nine studies among different occupational groups show significant associations between site-specific respiratory cancer and exposure to products containing formaldehyde. In addition, a group of professionals exposed to formaldehyde (anatomists, pathologists, embalmers and undertakers) have a significantly increased mortality from leukemias and brain neoplasms.

The National Cancer Institute (NCI) cohort study (1986) observed significant excesses in lung and nasopharyngeal cancers among U.S. workers occupationally exposed to formaldehyde at 10 industrial sites. NCI (1986), however, argued that the

lung cancer excesses provided little evidence of an association with formaldehyde exposure since the lung cancer risk did not increase consistently with either increasing intensity or cumulative formaldehyde exposure. EPA concluded, after reviewing the data, that the significant excesses in total lung cancer mortality, in analyses either with or without a latency period equal to or greater than 20 years, and together with nasopharyngeal cancer mortality among formaldehyde-exposed workers are meaningful despite the lack of significant trends with exposure.

An OSHA-NIOSH study of 11,030 garment workers exposed to formaldehyde for at least three months found a statistically significant excess in mortality from cancers of the buccal cavity and connective tissue. The study also found an excess in mortality for cancers of the trachea, bronchus and lung, pharnyx, bladder, leukemia and aleukemia, and other lymphopoietic neoplasms, but none was statistically significant.

Animal Studies. Formaldehyde has been found to be carcinogenic by inhalation in two strains of rats, and there is evidence of potential carcinogenicity in mice. A February 1986 drinking water study by Takahashi, Hasegana et. al. with formaldehyde showed evidence of compound related carcinogenicity in the stomach of the rat.

The CIIT study was the first long-term study reporting the carcinogenicity of formaldehyde in animals by the inhalation route. This study showed a statistically significant increase in nasal tumors in male and female Fischer 344 strain rats, with a dose-response relationship. Mice (C57BL/6 x $C3HF_1$) were also tested, and nasal tumors were also observed. The incidence of tumors in the mice was not statistically significant. However, the natural background rate for these tumors is very low, suggesting that the tumors were related to formaldehyde exposure.

A statistically significant number of squamous cell carcinomas were also observed in a study conducted by another group which exposed male Fischer 344 strain rats (same strain as used in the CIIT study) to formaldehyde by inhalation.

In another study with Sprague-Dawley male rats that were exposed by inhalation to a mixture of formaldehyde and hydrochloric acid, 25 out of 99 rats developed squamous cell carcinomas of the nose. In a second study in the same strain of rats, statistically significant numbers of squamous cell carcinomas of the nose were seen in rats exposed by inhalation to formaldehyde, and a mixture of formaldehyde and hydrochloric acid.

Two other chronic inhalation studies have been performed with formaldehyde in C3H mice and male Syrian golden hamsters. Although neither study demonstrated a carcinogenic effect, both studies had major shortcomings. In the mouse study too few animals survived past the first year. For both studies, incomplete histopathology of nasal tumors was performed.

In a 2-stage drinking water study in male Wistar rats, formaldehyde was shown to be a possible tumor promotor in the rat's stomach. The rats were first given a potent carcinogen (N-methyl-N-nitro-N-nitrosoguanidine (MNNG)) to initiate the formation of tumors in the stomach, and were then given a maintenance diet of drinking water that contained 0.5% formaldehyde Formaldehyde was found to significantly increase the incidence of adenocarcinomas in the rat stomach. Adenomatous hyperplasias and squamous cell papillomas were also found in the rat stomach.

The Agency is requiring oral oncogenicity and chronic toxicity testing because data are required to support tolerances or exemptions from tolerances.

Structure-Activity Relationship. Formaldehyde and paraformaldehyde are structurally similar to acetaldehyde, malondialdehyde and glycidaldehyde which have shown oncogenic activity in laboratory animals. Inhalation of acetaldehyde (which is closest in structure to formaldehyde) has produced tumors of the nose and larynx in hamsters and tumors of the nose in rats. Glycidaldehyde has produced skin tumors in mice in skin painting tests.

4. Mutagenicity. Formaldehyde has been shown to cause genetic changes in Drosophila larvae, fungi, viruses, yeast, mammalian cells and human cells. *In vitro* tests have detected induction of single strand breaks in DNA, a small increase in sister chromatid exchanges in mouse bone marrow, DNA-protein crosslinks, chromosome aberrations, and marginal results in a dominant lethal test. Based on the data reviewed by the Consensus Workshop on Formaldehyde, they concluded that formaldehyde acts as a weak mutagen (i.e., less than a ten-fold increase over background). However, none of these data are sufficient for FIFRA regulatory purposes. Gene mutation, structural chromosomal aberration and other genotoxic effects testing are required.

5. Developmental Toxicity. Inhalation studies in animals and epidemiological studies in workers have not demonstrated teratogenic effects. In a study by Marks et al. (1980) on mice, it was found that even at a dose which killed more than 50 percent of the dams, no adverse reproductive outcomes were observed except for an increase in the incidence of resorptions that was not statistically significant. None of the studies is adequate for FIFRA regulatory purposes. Teratogenicity studies by the oral route in the rat and rabbit are required.

6. Reproduction. In one study, prolonged diestrus, but no impairment of reproductive function was reported. This study is not adequate for FIFRA regulatory purposes. A 2-generation rat reproduction study is required.

7. General Metabolism. Formaldehyde is produced in mammalian systems by metabolism and thus is a normal constituent of body tissues. Such endogenous formaldehyde is produced from the degradation of serine and other amino acids. In dogs, cats, rabbits, guinea pigs and rats, the half-life of formaldehyde is estimated to be one minute. Formaldehyde that enters the body appears to convert rapidly to formate and carbon dioxide or to combine with tissue constituents. No general metabolism tests are required.

8. Ecological Effects. Formaldehyde (37% active ingredient) is slightly toxic to birds on an acute oral basis and practically nontoxic to birds on a subacute dietary basis. Formaldehyde is slightly toxic to warmwater fish, practically nontoxic to coldwater fish and slightly toxic to freshwater invertebrates. Formaldehyde is slightly to practically nontoxic to estuarine fish and moderately toxic to estuarine invertebrates.

Formulated formaldehyde products (containing 18% - 33% formaldehyde) that have been tested are practically nontoxic to highly toxic to estuarine and marine invertebrates and practically nontoxic to freshwater fish.

Environmental concentrations were estimated for the use patterns that had the potential to result in exposure to wildlife and aquatic organisms. Estimates were made for formaldehyde's use on grain seeds, forage fodder grasses, turf, and in secondary oil recovery systems. Estimates were made for paraformaldehyde's use on sugar maple tree tap holes and in oil well drilling muds. Estimates were made for the use of formaldehyde and paraformaldehyde as microbiocides in cooling towers, air scrubbers and industrial products. Use of formulations containing less than one percent formaldehyde and paraformaldehyde are not expected to pose a risk to fish and wildlife species from the formaldehyde constituent.

Seed Treatment and Forage Grasses. The use of formaldehyde is not expected to pose a hazard to terrestrial species.

Sugar Maple Trees. The Agency is unable to complete a hazard assessment to terrestrial species on the use of paraformaldehyde for tap holes in sugar maple trees until acute toxicity data to birds on the end-use product are submitted.

Oil Recovery Systems and Drilling Muds. A potential hazard may exist to estuarine species from the use of formaldehyde in secondary oil recovery systems and use of paraformaldehyde

in oil well drilling muds. Testing of additives containing formaldehdye used as oil field microbiocides indicates the additives are slightly toxic to highly toxic to estuarine invertebrates. Exposure to marine and estuarine species could occur from accidental spills and waste disposal. Data on the toxicity of all end-use oil field microbiocides to marine and estuarine species are required. Also, monitoring of formaldehyde levels in waters receiving residues from the use of the pesticide in secondary oil recovery systems (formaldehyde) and oil well drilling muds (paraformaldehyde) are required.

Turf. Assuming formaldehyde were applied directly to water (one acre pond with a water depth of six inches) at the application rate used on turf, the endangered species regulatory trigger for aquatic organisms (1/20 of the LC_{50}) would be exceeded for marine and freshwater fish and invertebrates. The exposure is overestimated because application to turf should not result in residues in water at as high a level as direct application to water. The Agency cannot accurately assess the hazard to aquatic species until residues in water adjacent to treated turf are determined. Chemical and environmental fate data are required. These data will be used to run a simulation model to estimate the runoff of the pesticide from the edge of the field and the fate of the pesticide in water. A residue monitoring study to determine the amount of formaldehyde entering aquatic systems under conditions of actual use on turf is reserved pending the modeling results. Usage estimates available to the Agency indicate little use of formaldehyde on turf, which reduces the risk to endangered species.

Cooling Tower and Industrial Biocide Uses. Microbiocides containing formaldehyde and paraformaldehyde are used in cooling towers, air scrubbers and industrial products such as metalworking fluids. Continuous discharge of industrial effluent potentially containing formaldehyde in shallow or enclosed bodies of water could result in environmental concentrations which may affect endangered species. The Agency is requiring monitoring studies to determine the levels of formaldehyde and paraformaldehdye in effluents from such facilities to evaluate risk to endangered species from these facilities.

Acute and subacute studies with paraformaldehyde in birds are required. Acute studies in freshwater fish, aquatic invertebrates, marine and estuarine organisms with formulated formaldehyde and paraformaldehyde products are required.

Chronic fish and aquatic invertebrate testing will be required if residue monitoring studies indicate residues at a level of concern. In addition, the previously mentioned

monitoring studies are required.

9. Environmental Fate. No data are available to assess the environmental fate of formaldehyde and paraformaldehyde. Degradation, metabolism, mobility, field dissipation and accumulation studies are required.

F. TOLERANCE REASSESSMENT

No tolerances have been established for residues of formaldehyde in or on food/feed items. 40 CFR 180.1032 exempts formaldehyde from the requirement of a tolerance for raw agricultural commodities that are used as animal feeds.

According to 40 CFR 180.1024, paraformaldehyde is exempted from the requirement of a tolerance for residues in or on sugar beets when applied to the soil not later than planting.

A food additive tolerance of 2 ppm has been established (21 CFR 193.330) for residues of formaldehyde in maple syrup resulting from use of paraformaldehyde to control microbial or fungal growth in maple tree tap holes.

Formulations containing one percent or less of formaldehyde or two percent or less of paraformaldehyde are exempt from the requirement of a tolerance when used as a preservative in pesticidal formulations applied to growing crops (40 CFR 180. 1001(d)).

There are no Canadian or Mexican tolerances or Codex maximum residue limits (MRLs) for residues of formaldehyde in or on agricultural commodities or in animal products. There is no Canadian or Mexican tolerance, nor is there a Codex MRL for residues of paraformaldehyde or formaldehyde in or on sugar maple syrup.

The Agency has evaluated the residue and toxicology data supporting the tolerances, exemptions from tolerances, and reviewed all uses of formaldehyde and paraformaldehyde. Based on the available data, the Agency concludes:

- No tolerances or exemptions from tolerances are established for residues of formaldehyde resulting from registered preplant, postplant and seed treatment uses. Plant metabolism data are required; if residues of concern are found, residue data will be required.

- Animal metabolism data are required because the available data suggest that formaldehyde may occur in treated feeds. If submitted studies show that naturally-occurring levels of formaldehyde in feed items or in tissues, milk, and eggs are similar to those resulting from formaldehyde treatment of feed items, then animal metabolism studies may be waived.

- Residue data are required to support the food additive tolerance of 2 ppm for formaldehyde residues in maple syrup.

- Current exemptions from the requirement of a tolerance for the preservative uses are not supported by data. If residues of concern are found in the plant metabolism study, residue data will be required.

An acceptable daily intake (ADI) has not been established for formaldehyde. When requested toxicological data are received, an ADI will be established. Based on requested residue data, a tolerance reassessment will be performed.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS

Based on review and evaluation of all available data on formaldehyde and paraformaldehyde, the Agency has made the following determinations. Refer to Section IV.D for specific language for label revisions.

1. The Agency has determined that formaldehyde and paraformaldehyde are pesticidally active when used as a preservative in pesticide formulations. Therefore, the Agency has classified them as active ingredients in such formulations. The labels of all pesticide products that contain formaldehyde or paraformaldehyde as a preservative must list the name and percent of the preservative constituent. Formaldehyde is contained in approximately 309 products as an inert ingredient and paraformaldehyde is contained in approximately 96 products as an inert ingredient. The following statement must also appear on the labels, "Formaldehyde (or paraformaldehyde) is present solely to preserve the pesticide formulation and does not otherwise contribute to the product's pesticidal activity".

Rationale: Many pesticide registrants add formaldehyde and paraformaldehyde to their formulations to preserve the pesticidal activity of the formulation by preventing deterioration by bacteria and fungi. Previously, formaldehyde and paraformaldehyde have been classified as inert ingredients when they were added as preservatives. However, according to FIFRA Section 2 (a) the term "active ingredient" means, among other things, "an ingredient which will prevent, destroy, repel or mitigate any pest". Therefore, the Agency concludes, based on the statutory definition of an active ingredient, that the preservatives, formaldehyde and paraformaldehyde, are active ingredients.

A registrant who believes that the formaldehyde/paraformaldehyde) in his formulation is not present at a level that would exert a preservative effect against bacteria/fungi (i.e., will not function as a biological preservative) may submit data demonstrating that this is so, and request that the formaldehyde/paraformaldehyde be designated an inert ingredient. If he chooses this course, the registrant must indicate his intention to do so within 90 days, and he must submit the supporting data within 9 months after receipt of this standard.

If the Agency agrees that the formaldehyde/paraformaldehyde is not present at levels sufficient to exert a pesticidal effect, the registrant will not be required to list the formaldehyde/paraformaldehyde as an active ingredient. In that case, the Agency's policy statement on inert ingredients

(in which formaldehyde and paraformaldehyde are categorized as List 1 inerts of toxicological concern) would govern the labeling requirements for that product.

2. The Agency has determined that formaldehyde and paraformaldehyde will not be placed in the Special Review process at this time. Available data are insufficient to determine whether Special Review criteria in §154.7 are met.

The Agency is requiring data under Section 3(c)(2)(B) of FIFRA to estimate the dietary risk and the non-dietary risk. After these estimates are made, the Agency will consider whether to place formaldehyde and paraformaldehyde in Special Review.

Rationale. Although formaldehyde has been classified by the Agency as a B1 oncogen, the Agency is able to estimate the risk to workers for only one agricultural situation (see section III.D). The risk to a worker in this situation was estimated to be less than 10^{-6} [B1].

The potential risks from other uses cannot be quantified at this time. The Agency lacks exposure data from other agricultural and non-agricultural uses of formaldehyde and paraformaldehyde. Data to assess the dietary and non-agricultural worker risks must be evaluated before a determination as to whether formaldehyde and paraformaldehyde should be placed in Special Review.

3. The Agency is not classifying formaldehyde and paraformaldehyde products for restricted use at this time. The Agency is requiring that product labels bear protective clothing and equipment statements that are adequate to mitigate the hazards of workers. After review of exposure data required by the Standard, the Agency will reconsider whether formaldehyde and paraformaldehyde products should be classified for restricted use. The specific types of protective clothing and equipment are specified in Section IV.D (5&6).

Rationale: The Agency believes that protective clothing and equipment, as well as other protective work practices designed to reduce exposures will mitigate the hazards such that restricted use is not warranted.

4. The Agency will require that appropriate protective clothing statements as specified in the labeling section be added to formaldehyde and paraformaldehyde product labels. Protective clothing is not required for air sanitizers, toilet or urinal sanitizers, all pellet/tablet formulations, crystalline, granular or impregnated paper formulations.

Products containing less than 1% formaldehyde or para-

formaldehyde in a formulation are also exempt. However, such products that contain other active ingredients must retain any protective clothing requirements already on the label for those active ingredients.

Rationale: Because of the wide variety of uses, protective clothing requirements were tailored to suit the use category. Refer to the Labeling Section IV.D (5&6) for protective equipment specifics. Exemptions from protective clothing requirements for certain use categories have been made because exposure is expected to be low. These requirements will reduce worker exposure, if the protective clothing and equipment is used and maintained properly.

5. The Agency is requiring that additional protective measures be placed on the labels of formaldehyde products intended for indoor fumigation uses, such as egg handling facilities and hospitals. If the concentration of formaldehyde exceeds 1 ppm (the OSHA 8-hour time-weighted average), a respirator is required for application or reentry. In addition, registrants must upgrade labeling to include precautionary statements, use directions, protective clothing, statements requiring use of NIOSH/MSHA respiratory protection devices approved for formaldehyde and paraformaldehyde when the concentration of the fumigant exceeds 1 ppm, use of specified direct-reading detector devices (identified by the registrant), statements requiring placarding of fumigated areas, aeration and reentry statements, and storage and handling, disposal and spill and leak procedures statements. These labeling statements are given in Section IV.D (5&6).

Rationale: Formaldehyde has been found to be carcinogenic in animal studies, there is limited evidence of carcinogenicity in humans, and it has been identified as an eye irritant and dermal sensitizer. The OSHA has set an 8-hour time-weighted average exposure limit of 1 part formaldehyde per million parts of air (29 CFR 1910.1048).

At this time, the Agency is not able to estimate the risk to workers from indoor fumigation uses of formaldehyde because exposure information are lacking. When these data are received, the Agency will reevaluate the 1 ppm level.

6. The Agency has determined that it will not impose a cancer hazard warning labeling statement requirement at this time.

Rationale: Although formaldehyde has been identified as a B1 oncogen, the Agency lacks exposure data from most agricultural and non-agricultural uses of formaldehyde and paraformaldehyde. Only surrogate exposure data were used as a basis for determining the risk to workers for one agricultural situation (see section III.D). Currently, oncogen warning statements are risk

driven. Since we do not have available actual exposure data to determine the risks associated with the pesticidal uses of these chemicals, we will reserve the right to consider this requirement after review of these data.

7. The Agency will consider new uses of formaldehyde and paraformaldehyde on a case-by-case basis. Applications for new use patterns must contain exposure data in order for the Agency to perform a risk assessment.

Rationale: New uses of formaldehyde and paraformaldehyde will be examined by the Agency on a case-by-case basis to determine exposure and risk because numerous data gaps have been identidied for residue chemistry, environmental fate and toxicology and because formaldehyde has been identified as a B1 oncogen.

8. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain of the data being required by the Agency are essential to resolve risk concerns, or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

§158.125 Residue Chemistry
- Plant Metabolism
- Storage Stability

§158.130 Environmental Fate
- Metabolism
- Photodegradation
- Dissipation
- Accumulation studies (Fish, rotational crops)

§158.135 Toxicology
- Oral oncogenicity
- Chronic toxicity

§158.140 Reentry Protection
- Inhalation exposure

§158.145 Ecological Effects
- Residue Monitoring (Turf, oil wells and industrial effluents)

9. The Agency will not impose a special label advisory statement for endangered species at this time. Four use patterns may possibly pose a risk to endangered species. These are use of formaldehyde on turf, products containing formaldehyde and paraformaldehyde that are discharged as

industrial effluents into shallow or enclosed bodies of water, use of formaldehyde in secondary oil recovery systems, and use of paraformaldehyde in oil well drilling muds (see Section III.E.8). Data being required will be used to estimate environmental concentrations. If levels are found to exceed the regulatory trigger for endangered species, a consultation with the Office of Endangered Species will be initiated.

Rationale: Most uses of formaldehyde and paraformaldehyde are not expected to pose a threat to endangered species. It is not possible at this time to estimate the environmental concentrations resulting from the four uses that may pose a risk to aquatic endangered and non-endangered species.

10. While data gaps are being filled, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing formaldehyde and paraformaldehyde may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration for previously registered use patterns simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(C)(7). Issuance of this Standard provides a mechanism for identifying data which then will be required to be submitted to maintain the registration of pesticide products containing formaldehyde and paraformaldehyde. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain formaldehyde or paraformaldehyde, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain formaldehyde or paraformaldehyde as an active ingredient.*/ Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing formaldehyde or paraformaldehyde provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The EPA Index to Pesticide Chemicals lists all registered uses, as well as approved maximum application rates and frequencies.**/

---

*/ Pesticide products in which formaldehyde or paraformaldehyde has previously been listed as an intentionally added inert ingredient are also covered by this standard. Such formaldehyde and paraformaldehyde ingredients have been redesignated as active ingredient by this standard.

**/ The EPA Use Index to Pesticide Chemicals may be purchased from the National Technical Information Service, ATTN: Order Desk, 5285 Port Royal Road, Springfield, Virginia 22161. Orders may be placed by telephone to National Technical Information Service at (703) 487-4650.

FORMALDEHYDE:

-Terrestrial food uses on:
Barley (grain crop), grain, millet (grain crop), oats (grain crop), potato, rye (grain crop), sorghum (grain crop), wheat (grain crop)

- Terrestrial Non-Food Crop uses on:
Ornamental plants, turf

- Aquatic-non food uses on:
Drains, secondary oil recovery systems, sewage systems, swimming pool related surfaces, shower rooms and locker rooms

- Indoors: Processed or Manufactured Products & Food or Feed Containers or Dispensers, Barley (grain crop)(for feed), corn (grain crop) (for feed), forage-fodder grasses (including hay and silage), legumes and other nongrass crops for forage-fodder, oats (grain crop)(for feed), sorghum (grain crop)(for feed), wheat (grain crop) (for feed), hatchery equipment, hatching egg treatment, kennels and pet animal quarters, laboratory animal quarters, stables, farm premises and equipment, livestock premises and equipment, livestock transportation vehicles, poultry house premises and equipment, poultry transporation vehicles, household premises and contents, sickroom premises and contents, commercial, industrial, and institutional premises and equipment (non-medical), commercial transporation vehicles, barber and beauty shop equipment and instruments, eating establishment equipment & utensils, eating establishment premises, dental instruments, hospital critical equipment, hospital premises and equipment, hospital rubber and plastic items, surgical instruments, veterinary hospital premises and contents, latex and resin emulsions, oil recovery drilling muds and packer fluids, paints, plastic and polymers, specialty products, (i.e. inks, dyes, ceramic glazes, waxes, polishes, cleansers, photographic solutions) bathroom premises, chemical and portable toilets, diaper pails, toilet bowls and urinals, carpets, laundry (hospital, commercial, and institutional), garbage containers, air sanitizers, biological specimens, cuspidors, environmental inanimate hard surfaces, vomitus.

FORMALDEHYDE (Continued):

-Preservative of pesticidal formulations.

PARAFORMALDEHYDE:

-Terrestrial food crop uses on:
Sugar maple (maple tree tapholes)

-Aquatic non-food:
Secondary oil recovery systems, lockers and locker rooms

-Indoor: (Pets & Domestic Animals & their Man-made Premises)
Hatchery equipment, hatching egg treatment, kennels and pet animal quarters, livestock premises and equipment, poultry house premises and equipment, household premises and contents, athletic and recreational equipment surfaces, commercial, industrial, institutional and public premises and equipment (non-medical), commercial transportation vehicles, barber and beauty shop equipment and instruments, eating establishment premises, metalworking cutting fluids, oil recovery drilling muds and packer fluids, bathroom premises, diaper pails, toilet bowls and urinals, laundry (mattresses, pillows and draperies), garbage containers, cadavers and casket.

-Preservative of pesticidal formulations

D. REQUIRED LABELING

In order to remain in compliance with FIFRA, manufacturing-use products and end-use products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing formaldehyde or paraformaldehyde may be released for shipment by the registrant after May 31, 1989 unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing formaldehyde or paraformaldehyde may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after May 31, 1990 unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for MPs must list the active ingredient as:

Formaldehyde or Paraformaldehyde

2. Products that contain formaldehyde or paraformaldehyde as a preservative must include the statement: "Formaldehyde (or paraformaldehyde) is present solely to preserve the pesticide formulation and does not otherwise contribute to the product's pesticidal activity".

3. Use Pattern Statements

All manufacturing-use products containing formaldehyde or paraformaldehyde must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

4. FUMIGATION REQUIREMENTS

All products containing formaldehyde (10% and above) or paraformaldehyde (25% and above) which are used for fumigation in commercial, industrial and institutional sites such as egg

handling facilities and hospitals should bear the following additional labeling:

a) Detailed use directions including the statements (1) "Persons working with the fumigant should be trained in fumigation operations" and (2) "Two persons should be present during the introduction of the fumigant, initiation of aeration and testing for reentry."

b) If the concentration of formaldehyde or paraformaldehyde in the working area, as measured by a direct reading device, does not exceed 1 ppm, no respiratory device is required. [The registrant must identify one or more detector devices suitable for use with the product and provide or reference instructions on its use.] If this concentration is exceeded at any time, all persons in the fumigated area must wear a respirator approved by NIOSH/ MSHA for formaldehyde or paraformaldehyde exposure.

c) "The applicator must placard or post all entrances to the fumigated areas with signs bearing in English and Spanish:
   - The signal word DANGER/PELIGO and the skull and crossbones symbol
   - The statement "Area under fumigation" DO NOT ENTER/NO ENTRE"
   - The date of fumigation
   - Name of fumigant used
   - Name, address, and telephone number of the applicator

   Only the applicator may remove the placards, and only when the concentration is below 1 ppm."

d) "After fumigation, treated areas must be aerated until the level of formaldehyde or paraformaldehyde is below 1 ppm. Do not allow entry into the treated area by any person before this time unless provided with a respirator approved by NIOSH/MSHA for formaldehyde or paraformaldehyde exposure."

e) "Wear chemical resistant rubber gloves when handling solid material. When fumigating an area, full-body clothing is required. Such clothing must be cleaned after each wearing or disposable clothing must be used."

f) "Storage and Handling Statements: Store in a cool, dry well ventilated area under a lock and key. Post as a pesticide storage area. Do not contaminate water, food or feed by storage or disposal. Persons moving or handling containers should wear protective clothing.

Open container only in a well ventilated area wearing protective clothing, gloves goggles or face shield and respiratory protection if air levels exceed 1 ppm."

g) Disposal Statements - Label statements must conform to the requirements of PR Notice 83-3, March 29, 1983.

h) "Spill and Leak Procedures - Evacuate immediate area of spill or leak. Use a respirator approved by NIOSH for formaldehyde or paraformaldehyde exposure for entry into affected area to correct problem. Move leaking or damaged containers outdoors or to an isolated location, observing strict safety precautions. Work upwind if possible. Wash fumigant into soil or cover with soil or other absorbent material. Do not permit entry into spill area or cleanup area by unprotected persons until concentration of fumigant is determined to be less than 1 ppm."

AND

Formaldehyde only:

"Pesticide wastes are toxic. Improper disposal of excess pesticide is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

OR

Paraformaldehyde only:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. MINIMUM PROTECTIVE EQUIPMENT REQUIREMENTS

Formaldehyde and paraformaldehyde products must bear statements requiring the following personal protective equipment, unless equivalent or more stringent requirements are already on the labeling.

a) All liquid formulations, including household products and all dusts and wettable powders containing 1% or greater of formaldehyde or paraformaldehyde: Chemical-resistant rubber gloves.

b) All products for agricultural uses, including hatchery products, oil recovery system products and kennel and pet quarters: Chemical-resistant rubber gloves.

c) All fumigant products: A NIOSH/MSHA respirator approved for formaldehyde exposure if concentration is above 1 ppm.

d) All products applied using a spray (except aerosol products) where mist is likely to occur: A protective suit covering the entire body except the feet, hands and head, OR long pants, long sleeve shirt and chemical resistant apron.

e) Manufacturing use products or products for repackaging: A NIOSH/MSHA respirator approved for formaldehyde exposure, chemical resistant boots or shoe covers, chemical resistant gloves, and goggles (if a full face respirator is not used).

Personal protective statements are not required for air sanitizers, toilet and urinal sanitizers (those that act by the flushing process) pellet and tablet formulations, crystalline, granular and impregnated paper products.

6. ENVIRONMENTAL HAZARDS STATEMENTS

All Formaldehyde Manufacturing Use and Formaldehyde/Paraformaldehyde Microbiocide, MetalWorking, Oilfield, Pulp & Paper Mill Products

Labels for these manufacturing or end-use products must bear the following environmental hazards statement:

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

7. Additional Statements for End-Use Products

a) In addition to the above statement, products with outdoor uses that have an LC_{50} to fish or aquatic invertebrates of <0.1 ppm must include the statement, "This product is toxic to aquatic organisms."

b) Products recommended for use on turf and other nonseed treatment uses must include the following statement on the labeling:

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by disposal of equipment washwaters."

c) Products recommended for seed treatment uses should include the following statement on the labeling:

"Cover, scavenge, or incorporate spills of treated seeds. Do not contaminate water by disposal of equipment washwaters."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the ingredients identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing formaldehyde or paraformaldehyde as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2].

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

---

[2] Data requirements are listed in the two Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use and end-use products. The data in Table A need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

B. Manufacturing use products containing formaldehyde or paraformaldehyde as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing formaldehyde or paraformaldehyde alone or in combination with other active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. The labeling requirements specified for end use products in Section IV.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A.

4. If eligible for the formulator's exemption[3], the data requirements in Table A are not required.

---

[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product -specific data for the registered manufacturing use and end-use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change source of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing formaldehyde or paraformaldehyde[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

---

[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing these ingredients after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing the active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you or your agent must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted.

Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortiu;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. <u>You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI</u>. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

a. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

b. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA section 3(c)(2)(B) in formaldehyde/paraformaldehyde. Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. <u>You request a waiver of the data requirement</u>. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label or chemicals which are no longer in your product.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient

studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in IX.E.

EPA will view failure to request an extension before the data submission deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registration in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review. All labeling changes must appear on all products released for shipment by registrants by May 31, 1989 and on all products distributed or sold by any person by May 31, 1990.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing formaldehyde or paraformaldehyde as an active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

---

[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing formaldehyde or paraformaldehyde in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months of receipt of this document, you must submit to the Product Manager:

Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

3. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing formaldehyde or paraformaldehyde alone or in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing formaldehyde or paraformaldehyde either as sole active ingredient or in combination with other active ingredients.

Applications for full Federal registration of intrastate products are required to be submitted no later than July 31, 1988.

E. Addresses

The required information must be submitted to the following address:

John Lee, Product Manager 31
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

GUIDE TO TABLES

Tables A and B contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation[2]	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	N/A	N/A	Yes	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	N/A	N/A	Yes	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	N/A	N/A	Yes	12 Months
62-2 - Certification of Ingredient Limits	TGAI	All	N/A	N/A	Yes	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	All	N/A	N/A	Yes	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	N/A	N/A	Yes	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation[2]	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-3 - Physical State	TGAI	All	N/A	N/A	Yes	6 Months
63-4 - Odor	TGAI	All	N/A	N/A	Yes	6 Months
63-5 - Melting Point	TGAI	All	N/A	N/A	Yes[4]	6 Months
63-6 - Boiling Point	TGAI	All	N/A	N/A	No[5]	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	N/A	N/A	Yes[4]	6 Months
63-8 - Solubility	TGAI or PAI	All	N/A	N/A	Yes	6 Months
63-9 - Vapor Pressure	PAI	All	N/A	N/A	Yes	6 Months
63-10 - Dissociation constant	PAI	All	N/A	N/A	Yes	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	N/A	N/A	Yes	6 Months
63-12 - pH	TGAI	All	N/A	N/A	Yes	6 Months
63-13 - Storage Stability	TGAI	All	N/A	N/A	Yes	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation[2]	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.120 Product Chemistry (Continued)						
Other Requirements:						
64- 1 - Submittal of samples	TGAI, PAI	All	N/A	N/A	No	

1/ The test substance for the TGAI is 100% formaldehyde and paraformaldehyde.
2/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.
3/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
4/ Not required for formaldehyde because the technical is a gas at room temperature.
5/ Not required for formaldehyde because the technical is a gas at room temperature. Not required for paraformaldehyde because the technical is a solid at room temperature.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame For Submission[1]
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	See Prod. Chem. table			
171-3 - Directions for Use	—	Yes	(Use Index)		
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	No		Yes[2]	18 Months
- Livestock	PAIRA & Plant Metabolites	Partial	00082145,00123774	Yes[3]	18 Months
171-4 - Residue Analytical Method					
- Plant residues	TGAI & Metabolites	Partial	00124679,0082153	Yes[4]	15 Months
- Animal residues	TGAI & Metabolites	Partial	00124679	Yes[4]	15 Months
- Storage Stability	TGAI & Metabolites	No		Yes[5]	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.125 Residue Chemistry (Cont'd)					
171-4 - Magnitude of the Residue Studies for Each Food Use					
- Preplant & Postplant Fumigation					
° Root & tuber vegetables groups	TEP	No		Reserved[6]	15 Months
° Leaves of root and tuber vegetables group	TEP	No		Reserved[6]	15 Months
° Bulb vegetables group	TEP	No		Reserved[6]	15 Months
° Leafy vegetables group	TEP	No		Reserved[6]	15 Months
° Brassica (cole) leafy vegetables group	TEP	No		Reserved[6]	15 Months
° Legume vegetables (succulent or dried) group	TEP	No		Reserved[6]	15 Months
° Foliage of legume vegetables	TEP	No		Reserved[6]	15 Months
° Fruiting vegetables (except cucurbits) group	TEP	No		Reserved[6]	15 Months
° Cucurbit vegetables group	TEP	No		Reserved[6]	15 Months
° Citrus fruits group	TEP	No		Reserved[6]	15 Months
° Pome fruits group	TEP	No		Reserved[6]	15 Months
° Stone fruits group	TEP	No		Reserved[6]	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame For Submission[1]
§158.125 Residue Chemistry					
- Preplant & Postplant Fumigation (Cont'd)					
° Small fruits and berries group	TEP	No		Reserved[6]	15 Months
° Tree Nuts group	TEP	No		Reserved[6]	15 Months
° Cereal grains group	TEP	No		Reserved[6]	15 Months
° Forage, fodder & straw of cereal grains group	TEP	No		Reserved[6]	15 Months
° Grass forage, fodder & hay group	TEP	No		Reserved[6]	15 Months
° Non-grass animal feeds (forage, fodder, straw & hay) group	TEP	No		Reserved[6]	15 Months
° Miscellaneous crops: asparagus, cotton (non-food), okra, olives peanuts, & tobacco(non-food)	TEP	No		Reserved[6,20]	15 Months
- Seed Treatment	TEP	No		Reserved[7,8,9,10,11]	15 Months
- Postharvest Grain Treatment	TEP	Partial	00123774,00124679	Reserved[12]	
- Postharvest Forage, Fodder, & Hay Treatment	TEP	Partial	00124679	Reserved[13,14,15]	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame For Submission[1]
§158.125 Residue Chemistry					
- Sugar Maple Tree Taphole Treatment	TEP	No		Reserved[16]	15 Months
- Mushrooms	TEP	No		Reserved[6,21]	15 Months
171-4 - Magnitude of the Residue in Animals etc.					
- Meat/Milk/Poultry/ Eggs	TGAI or Plant Metabolites	Partial	00124679	Reserved[17]	15 Months
-Food Handling Establishments	EP	No		Yes[18,19]	12 Months

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
2/ Data depicting the distribution and metabolism of [^{14}C] formaldehyde (i) in mature potatoes grown from treated seed pieces; (ii) in wheat grain and forage harvested at maturity following seed treatments; and (iii) in peanut forage and hay sampled at several time intervals beginning immediately after postharvest application; all applications must be made at rates sufficiently high to permit complete characterization of ^{14}C-residues.

3/ Metabolism studies utilizing ruminants and poultry. Animals must be dosed for three days with [^{14}C] formaldehyde at levels sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be terminated within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat.

§158.125 Residue Chemistry

4/ Residue methods are required which are suitable to provide data demonstrating the identity and magnitude of all residues of concern resulting from the registered uses and also provide a means of enforcement of any tolerances deemed necessary. All methods selected for enforcement purposes must be subjected to EPA method tryouts.

5/ All of the requested residue data in this standard must be accompanied by information on the duration and conditions of sample storage prior to residue analysis and data which describe the stability of residue under the storage conditions used. Storage stability data will be required for formaldehyde and any metabolites which are determined from the requested metabolism data to constitute residues of concern.

Reserved data requirements: The timeframe for data which are reserved begins when the study is required.

6/ If residues of concern are found in or on agriculture crops in the studies requested for Nature of the Residues in/on plants, the following residue data will be required.

Data depicting residues of concern in or on representative commodities in this crop group as indicated in 40 CFR 180.34 after a single preplant fumigation with the 37% SC/L formulation at 435.6 gal/A 2-3 days before planting of seed and a single postplant, plant bed fumigation (required for crops grown or started in cold frames, frames, flats, greenhouses or hot beds only) with the same formulation at 17 gal/A after the seeds are planted and covered. Tests must be conducted in major U. S. production regions for each crop.

7/ Specify all use rates in terms of lb ai/100 gal water as well as pints product per 100 gal water.

8/ Depiction of residues of concern in or on corn, rice, sorghum, and wheat at maturity after seed treatments at the maximum permissible rate. Upon fulfillment of these data requirements an appropriate Cereal Grains crop group tolerance will be established, unless, the registered uses (see above) differ significantly for crops in the Cereal Grains, in which case residue data will also be required for each crop with significantly different uses. Data for each crop must be geographically representative of total U. S. production.

9/ Depiction of residues of concern in or on potatoes at maturity after seed piece treatments at the maximum permissible rate and duration of treatment. Tests must be conducted in CA, CO, ID, ME, ND, WA, and WI; states which adequately represent total U. S. potato production (Agricultural Statistics, 1984, p. 1656, preliminary 1983 data).

§158.125 Residue Chemistry

10/ Depiction of residues of concern in or on onions at maturity after seed treatment at the maximum permissible rate, and duration of treatment. Tests must be conducted in OR, the only state currently having a registered use.

11/ Depiction of residues of concern in or on garlic at maturity after seed treatment of 24 pints/100 gal water of the 37% SC/L formulation. Tests must be conducted in CA.

12/ If the results of the studies required for Nature of the Residues in Animals and Magnitude of the Residue in Animals show that residues of concern will occur in animals due to registered stored commodities applications, tolerances must be established. The following residue data will be required for each of the crops with a registered stored commodity use prior to the establishment of a tolerance.

Representative commodities of the Cereal Grains Group, corn, rice, sorghum, and wheat, (barley or oats should be substituted for rice since there is no registered use for rice) must be treated within six hours after harvest with 1.6, 2.0, 2.6, and 3.0 lb ai/2000 lb grain using the 10% RTU formaldehyde formulation. The above rates should be applied respectively to corn with <20%, 21-30%, 31-35%, and 36-40% moisture content utilizing a pressure sprayer system. Residues of concern must be determined in grain samples taken at regular intervals beginning immediately after harvest.

13/ For the Foliage of the Legume Vegetables Group, data depicting residues of concern in or on forage of any variety of beans (Phaseolus spp.), peas, and soybeans are required. Forage not in storage must be treated with the following rates: 1 lb ai/ton (500 ppm) wet hay at 20 to 24% moisture, 1000 ppm wet hay at 25 to 29% moisture, and 150 ppm wet hay at 30 to 35% moisture. Additionally tests must be conducted in which 2 lbs ai/ton (1000 ppm) fresh forage are applied by metering with forage in soils or pits. A sufficient number of tests must be conducted to adequately characterize the maximum residue level in or on Foliage of Legume Vegetables resulting from the registered uses.

14/ For the Cereal Grains Group, data depicting residues of concern in or on forage of corn, wheat, and any other cereal grain crop, such as sorghum, are required. The data must be collected as outlined above in the data requirements for the Foliage of Legume Vegetables Group.

§158.125 Residue Chemistry

15/ For the Non-grass Animals Feeds (forage, fodder, straw, and hay) Group, data depicting residues of concern in or on alfalfa and clover are required. The data must be collected as outlined above in the data requirements for the Foliage of Legume Vegetables Group.

16/ If the requested plant metabolism studies demonstrate that residues of concern will result from the use of paraformaldehyde, the following residue data will be required. Depiction of residues of concern in sugar maple syrup processed from maple tree sap after application of paraformaldehyde at 0.0088 oz. ai/taphole. Mature trees should be tapped in February or March and samples obtained (>1 quart/sample) throughout the sap run period.

17/ If the required animal metabolism data (refer to Nature of the Residues in Animals for details) demonstrate that detectable residues of concern of formaldehyde occur in animals, then additional data will be required; specific data requirements regarding the magnitude of the residues in animals will be detailed at that time.

18/ The 0.2% RTU formaldehyde formulation must be applied undiluted with scrubbing to the surface of pots and pans rinsed two minutes after application. The 37% SC/L formuation must be diluted to a solution containing 1380 ppm formaldehyde and used liberally to wash the inside of refrigerators. The 34% SC/L MAI formulation must be applied at a concentration of 523 ppm by spraying all surfaces until completely wetted (alternatively, the registrant may propose a maximum use rate per unit floor area or surface area of treated surfaces, and apply the maximum lb ai in the required tests, in two different types of eating establishment premises, such as restaurant and school dining areas). The registrant must determine, from the above applications, residues of concern from direct deposition of spray droplets on food, volatilization and subsequent absorption by foods, and all other possible modes of exposure of foods and residue transfer routes as outlined in the EPA Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, 171-4(C)(5). Representative food samples must be examined for residues of concern from these possible modes of exposure; the food must include an oily food (eg., butter), baked cereal product, beverages, raw and processed meats, and fresh fruits and vegetables (lettuce). Tests must also include conditions of possible misuse of formaldehyde and exaggerated exposure, eg., applying an exaggerated rate or direct exposure of foods to the formaldehyde solution applied (Refer to EPA Pesticide Guidelines for details of the type of data required.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

§158.125 Residue Chemistry

19/ The 95% Cr formulation of paraformaldehyde must be applied at 0.31 lb of formulation per 756 ft^3 as a fumigant in two different types of eating establishment premises such as restaurant and school dining areas. Possible residues transfer routes and residues of concern on representative foods must be examined as outlined above in the formaldehyde data requirements.

20/ Data depicting formaldehyde residues of concern in or on these miscellaneous crops following foliar application (and at postharvest for asparagus) of the formaldehyde FIC formulation at representative geographic locations according to the labeling directions at the maximum registered rate. Samples of all raw agricultural commoditie from each crop group must be collected at the shortest interval after application in which they could be used for food or feed purposes.

21/ Data depicting formaldehyde residues of concern in or on mushrooms collected following the last of multiple soil applications of the formulation registered for this use at 0.0294 lb. ai/100 lb. soil. A maximum permissible number of applications must be proposed.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,D F,G,H	No		Yes	9 Months
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,D F,G	No		Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A,B,G	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	E,F,I	No		No[2]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,E F,G,H	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes[3]	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D,G	No		Yes[4]	27 Months Progress reports: 12 & 24 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D,G	No		Yes[4]	27 Months Progress reports: 12 & 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.130 Environmental Fate - Continued						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,D,E F,G,H	No		Yes	12 Months
163-2 - Volatility (Lab)	TEP	A,E,F,I	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A,E,F,I	No		Reserved[5]	15 Months
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	D,G	No		Yes[4]	27 Months
164-3 - Forestry	TEP	G	No		Yes	27 Months
164-5 - Soil, Long-term	TEP	A	No		Reserved[6]	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months Progress reports: 12, 24 & 36 months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved[7]	50 Months
165-4 - In Fish	TGAI or PAIRA	A,B D,G	No		Yes	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.130 Environmental Fate - Continued						
ACCUMULATION STUDIES: (Continued)						
165-5 - In Aquatic Non-Target Organisms	TEP	D,G	No		Yes[8]	12 Months

1/ Data must be submitted within the time frame indicated, based on the date of the Guidance Document.
2/ Data not required based on label statements concerning ventilation of indoor areas during fumigation and prior to worker reentry.
3/ Not required if an acceptable anaerobic aquatic metabolism study is submitted.
4/ Not required if registrant can demonstrate that no direct discharge of water containing formaldehyde or paraformaldehyde occurs.
5/ Data deferred pending receipt of laboratory volatility data. Timeframe will begin when study is required.
6/ Requirement for data is deferred pending the receipt of data on aerobic soil metabolism and terrestrial field dissipation. Timeframe will begin when the study is required.
7/ This study is reserved pending the results of the confined study.
8/ Not required if laboratory fish accumulation study shows no bioaccumulation.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B,F G	No	_____	No	
132-1 - Soil Dissipation	TEP	A,B,F G	No	_____	No	
133-3 - Dermal Exposure	TEP	A,B,F G	No	_____	No	
133-4 - Inhalation Exposure	TEP	E,I	No	_____	Yes[2]	27 Months Protocol: 3 Months Progress reports: 12 & 24 Months

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
2/ Data are required for greenhouse and indoor uses, such as egg hatcheries and hospitals. A protocol should be submitted, prior to developing data.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission[1]
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,D,I	Partial	119785, 65508 137297, 127060 127059, 75459 127500, 66997	Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,D,I	Partial	65508, 137247 127060, 127059 65511, 122750 79674, 119785	Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B,D,I	Partial	69393, 127500 137297, 127059 56308, 82134 132494, 82130 56309, 117674 82132, 119785	Yes	9 Months
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding:						
- Rodent,	TGAI	A,B,D,I	No		Yes	15 Months
- Non-rodent (Dog, Chicken)	TGAI	A,B,D,I	No	127069	Yes	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.135 Toxicology - Continued						
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,D,I	Partial	51255	Yes	12 Months
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B,D,I	No		Reserved[2]	15 Months
82-4 - 90-Day Inhalation: - Rat	TGAI	A,B,D,I	Partial	82134	Yes	15 Months
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species: - Rodent, and	TGAI	A,B,D,I	Partial	GS556-001	Yes	50 Months Progress reports: 12, 24 & 36 Months
- Non-rodent (Dog)	TGAI	A,B,D,I	No		Yes	50 Months Progress reports: 12, 24 & 36 Months
83-2 - Oncogenicity -						
- Inhalation 2 species: - Rat (preferred)	TGAI	A,B,D,I	Yes	GS556-001	No	
- Mouse (preferred)	TGAI	A,B,D,I	Yes	GS556-001	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.135 Toxicology - Continued						
CHRONIC TESTING						
83-2 - Oncogenicity (Continued)						
- Oral (gavage) 2 species: - Rat (preferred)	TGAI	A,B,D,I	No		Yes	50 Months Progress reports: 12, 24 & 36 Months
- Mouse (preferred)	TGAI	A,B,D,I	No		Yes	50 Months Progress reports: 12, 24 & 36 Months
83-3 - Teratogenicity - 2 species: - Rat - Rabbit	TGAI	A,B,D,I	No		Yes	15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,D,I	No		Yes	39 Months Progress reports: 12, 24 & 36 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,D,I	Partial	132492 GS556-001	Yes	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING (Continued)						
84-2 - Structural Chromosomal Aberration	TGAI	A,B,D,I	Partial	GS556-001	Yes	12 Months
84-4 - Other Genotoxic effects	TGAI	A,B,D,I	Partial	GS556-001	Yes	12 Months
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B,D,I	Yes	124672, 82147	No	
85-2 - Dermal Penetration	PAI or PAIRA	A,B,D,I	No		Yes	12 Months
86-1 - Special Requirement Domestic Animal Safety	Choice	A,B,D,I	No		Reserved[3]	Variable

1/ Data must be submitted within the time frame indicated, based of the date of the Guidance Document.
2/ Data requirement is contingent upon the results of the subchronic 21 day dermal test. Timeframe begins when the study is required.
3/ Data from tests on domestic animals may be required to support the registration of an end-use product if cats, dogs, cattle, pigs, sheep, or other domestic animals will be exposed through direct application for pest control and consumption of treated feed. The applicant should contact the Agency to determine what toxicological data are required. Timeframe begins when the study is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Single-Dose Oral LD_50	Formaldehyde					
	TGAI	A,B,D,G H,I[5]	Yes	00148774	No	
	Paraformaldehyde					
	TGAI	A,B,D H,(I)[5]	No		Yes[2]	9 Months
71-2 - Avian Dietary LC_50	Formaldehyde					
- Upland Game Bird and	TGAI	A,B,D,G H,(E,I)[5]	Yes	00148773	No	
- Waterfowl	TGAI	A,B,D G,H	Yes	00148775	No	
	Paraformaldehyde					
- Upland Game Bird and	TGAI	A,B,D H,(I)[5]	No		Yes[2]	9 Months
Waterfowl	TGAI	A,B,D,H	No		Yes[2]	9 Months
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_50	Formaldehyde					
	TGAI	A,B,D,G,H (E,I)[5,6]	Yes	00132485	No	
	TEP	D	Partial	00101857	Yes[3]	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING _ Continued						
72-1 - Freshwater Fish LC_{50} (continued)	Paraformaldehyde					
	TGAI	A,B,D,H (I)[5]	No		No[7]	
	TEP	D	Partial	00101857	Yes[3]	9 Months
72-2 - Aquatic Invertebrate Acute EC_{50}	Formaldehyde					
	TGAI	A,B,D,G (E,I)[5]	Yes	00148772	No	
	TEP	D	No		Yes[3]	9 Months
	Paraformaldehyde					
	TGAI	A,B,D,H (I)[5]	No		No[7]	
	TEP	D	No		Yes[3]	9 Months
72-3 - Estuarine and Marine Organism Acute LC_{50}	Formaldehyde					
	TGAI	(A,B)[5]D	Yes	00148770	No	
	TEP	D	Partial	00128086 00126394 00126396	Yes[3]	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING - Continued						
72-4 - Fish Early Life Stage, and Aquatic Invertebrate Life Cycle Studies	Formaldehyde TGAI	D	No		Reserved[9]	15 Months
70-1 - Special Test Residue Monitoring	Formaldehyde & Paraformaldehyde					
- Turf application	TEP	B	No		Reserved[4]	12 Months
- Oil wells and Industrial effluents	TEP	D	No		Yes[8]	12 Months

1/ Data must be submitted within the indicated time frame, based on the date of the Guidance Document.
2/ Studies must be submitted using technical paraformaldehyde, the solid polymer of formaldehyde.
3/ Data from testing with the applicant's end-use product is required to support the registration of each end-use product for which: an ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms. This test must therefore be conducted using all formulations registered for use in oil drilling and recovery operations.
4/ Because of the high application rates of formaldehyde on turf, and the practice of irrigation immediately following application, a residue monitoring study will be reserved pending the receipt of environmental fate data and the results of SWRRB-EXAMS simulation.
5/ Required to support registrations of the manufacturing end-use product.

§158.145 Wildlife and Aquatic Organisms - Continued

6/ Required for only one species of fish (cold water or warm water) only.

7/ Testing of technical paraformaldehyde on aquatic species is not required because in solution it will become formaldehyde.

8/ Monitoring of formaldehyde levels in waters receiving residues from the use of the pesticide (formaldehyde or paraformaldehyde) in secondary oil recovery systems and other industrial effluents such as cooling towers, air scrubbers, metalworking fluids and oil well drilling muds, is required. Based on use information (i.e., geographic sites and amount used, etc.) registrants will be required to develop acceptable protocols (within 3 months) to sample a representative number of the above sites. Studies are required to assess the release of formaldehyde into the environment due to concern for chronic effects to aquatic organisms. Any protocol developed for monitoring this chemical must consider the following requirements: (i) use of standard analytical methods, i.e., HPLC or MSGC to measure formaldehyde, (ii) sites selected for sampling must be where formaldehyde is currently being used and must be representative of small and large facilities and/or volume, (iii) sites selected must also be representative of (1)a range in volume of the receiving water bodies or rivers and (2) freshwater and estuarine ecosystems; (iv) samples taken for analysis must be taken before treatment, after treatment, and from receiving waters, (v) sampling should be done at regular intervals for a long enough period of time to account for such things as seasonal variations.

9/ Fish early life stage and aquatic invertebrate life cycle studies are reserved pending the completion of aquatic residue monitoring studies.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FORMALDEHYDE

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation[2]	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	N/A	N/A	Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	N/A	N/A	Yes[4,5]	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	N/A	N/A	Yes[6]	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	N/A	N/A	Yes	12 Months
62-2 - Certification of Limits	MP	All	N/A	N/A	Yes[7]	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	N/A	N/A	Yes[8]	12 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FORMALDEHYDE

Data Requirement	Test Substance[1]	Use Patterns	Does EPA Have Data?[2]	Bibliographic Citation[2]	Must Additional Data be Submitted?	Time Frame for Submission[3]
§158.120 Product Chemistry (Continued)						
Other Requirements:						
64- 1 - Submittal of samples	MP	All	N/A	N/A	No	

1/ Test Substance: The 37%, 44% and 45% Formulation Intermediate products serve as the manufacturing-use products. (There are not any registered paraformaldehyde manufacturing use products.)
2/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.
3/ Data must be submitted within the time frame indicated, based on the date of the Guidance Document.
4/ Details of the manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, purification procedures and quality control measures.
5/ The name and address of the manufacturer, producer, or supplier of each beginning material used to manufacture the formulation intermediate and the technical product from which it is produced. A copy of all available specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of each beginning material used to produce the formulation intermediate and the formaldehyde technical from which it is produced.
6/ A discussion of each impurity believed to be present at >0.1%, based on knowledge of the beginning materials, all possible chemical reactions and any contamination.
7/ Upper and lower limits must be provided, validated and certified for formaldehyde and each intentionally added inert ingredient. Upper and lower limits must be provided and validated for each impurity associated with formaldehyde present at >0.1% (w/w) of the technical material.
8/ Quantitative methods to determine formaldehyde and all impurities for which a certified limit is required in the formulation intermediates. Each method must be accompanied by validation studies of the precision and accuracy of the method.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,D,I	Partial	119785,65508 137297,127060 127059,75459 127500,66997	Yes	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,D,I	Partial	65508,137247 127060,127059 65511,122750 79674,119785	Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B,D,I	Partial	69393,127500 137297,127059 56308,82134 132494,82130 56309,117674 119785,82132	Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,D,I	Partial	132490,65516 66997,127059 127071,127060 119785,127500 60059,132488 43591,65508 137297	Yes	9 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FORMALDEHYDE AND PARAFORMALDEHYDE

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission[1]
§158.135 Toxicology (Cont'd)						
81-5 - Primary Dermal Irritation - Rabbit	MP	A,B,D,I	Partial	124552,43592 65517,66997 65514,137297 127503,127060 127059,134117 75459	Yes	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B,D,I	Partial	132494,96223 54714	Yes	9 Months

1/ Data must be submitted within the time frame indicated, based on the date of the Guidance Document.

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .,' "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for

whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semi-solid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to

other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive, corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days, irritation persisting for 7 days.	No corneal opacity, irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the

basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency. the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Formaldehyde/Paraformaldehyde Standard

MRID	CITATION
00043591	Abbott, D.D. (1970) Eye Irritation--Rabbit: Report L&H 72158-2. (Unpublished study including letter dated May 19, 1970 from D.D. Abbott to Charles Kaitz, received Jun 1, 1970 under 6035-33; prepared by La Wall and Harrisson Research Laboratories, Inc., submitted by Vineland Laboratories, Inc., Vineland, N.J.; CDL: 107119-A)
00043592	Abbott, D.D. (1970) Primary Skin Irritation--Rabbit: Report L&H 72158-2. (Unpublished study including letter dated May 19, 1970 from D.D. Abbott to Charles Kaitz, received Jun 1, 1970 under 6035-33; prepared by La Wall and Harrisson Research Laboratories, submitted by Vineland Laboratories, Inc., Vineland, N.J.; CDL:107119-B)
00051255	Cotchan, T.; Siegmund, E. (1961) Letter sent to S. Krop dated May 12, 1961: Glutaraldehyde, local toxicity. (Unpublished study received May 12, 1961 under unknown admin. no.; prepared by Ethicon, Inc., submitted by Surgikos, Inc., Arlington, Tex.; CDL:104808-A)
00054714	Marzulli, F.N.; Maibach, H.I. (1973) Antimicrobials: Experimental contact sensitization in man. Journal of the Society of Cosmetic Chemists 24:399-421. (Also in unpublished submission received Nov 16, 1976 under 1258-840; submitted by Olin Corp., Stamford, Conn.; CDL:226870-X)
00056308	Skog, E. (1950) A toxicological investigation of lower aliphatic Aldehydes: I. Toxicity of Formaldehyde, Acctaldehyde, Propionaldehyde and Butyraldehyde; as well as of Acrolein and Crotonaldehyde. Acta Pharmacologica et Toxicologica 6:299-318. (Also in unpublished submission received Oct 6, 1976 under 52-231; submitted by West Chemical Products, Inc., Lynbrook, N.Y.; CDL: 226499-A)
00056309	Carpenter, C.P.; Smyth, H.F., Jr.; Pozzani, U.C. (1949) The assay of acute vapor toxicity, and the grading and interpretation of results on 96 chemical compounds. Journal of Industrial Hygiene & Toxicology 31(6):343-346. (Also in unpublished submission received Oct 6, 1976 under 52-231; submitted by West Products, Inc., Lynbrook, N.Y.; CDL:226499-B)
00060059	Baroid (19??) Primary Eye Irritation Data Summary. (Unpublished study received Mar 28, 1973 under 17664-15; CDL:226787-B)

MRID CITATION

00065508 Cannon Laboratories, Incorporated (1975) Summary of Preservative DF-35 # 3T1522: Laboratory Nos. 5E-6921, 5E-6923, 5E-6924, 5E-6922. (Unpublished study received Jan 11, 1977 under 10000-4; submitted by Hallemite Lehn & Fink, Montvale, N.J.; CDL: 229296-A)

00065511 Becker, J.; Parke, G.S.E. (1975) Acute Dermal LD50 Study on Rabbits. (Unpublished study received Jan 11, 1977 under 10000-4; prepared by Cannon Laboratories, Inc., submitted by Hallemite Lehn & Fink, Montvale, N.J.; CDL:229296-D)

00065514 St. Pierre, F.; Parke, G.S.E. (1976) Report on Primary Dermal Irritation Study in Rabbits: Laboratory No. 6E-4231. (Unpublished study received Jan 11, 1977 under 10000-4; prepared by Cannon Laboratories, Inc., submitted by Hallemite Lehn & Fink, Montvale, N.J.; CDL:229296-G)

00065516 Becker, J.; Parke, G.S.E. (1976) Report on Rabbit Eye Irritation: Laboratory No. 6E-3481. (Unpublished study received Mar 31, 1977 under 10000-5; prepared by Cannon Laboratories, Inc., submitted by Hallemite Lehn & Fink, Montvale, N.J.; CDL:229284-B)

00065517 Becker, J.; Parke, G.S.E. (1976) Report on Primary Dermal Irritation Study in Rabbits: Laboratory No. 6E-3480. (Unpublished study received Mar 31, 1977 under 10000-5; prepared by Cannon Laboratories, Inc., submitted by Hallemite Lehn & Fink, Montvale, N.J.; CDL:229284-E)

00066997 McGee, G.J.; Freeman, L. (1971) LD50--Rats; Primary Skin Irritation--Rabbits; Primary Eye Irritation--Rabbits: Experimental Reference No. A-451. (Unpublished study received Mar 13, 1972 under 10865-1; prepared by KG Laboratories, Inc., submitted by DDR Pharmaceutical Corp., Copiaque, N.Y.; CDL:100197-A)

00069393 McGee, G.J.; Goldhamer, R.E. (1972) Acute Inhalation: Experimental Reference No. A-451. (Unpublished study received Mar 15, 1972 under 10865-1; prepared by Biometric Testing, Inc., submitted by DDR Pharmaceutical Corp., Copiaque, N.Y.; CDL:100196-A)

00075459 Biesemeier, J.A. (1976) Report: WARF Institute No. 6041564. (Unpublished study received Jul 12, 1976 under 1677-77; submitted by Economics Laboratory, Inc., St. Paul, Minn.; CDL:233683-A)

00079674 Moldovan, M. (1971) Rabbit Eye Irritation Study: I.B.L. No. 8870. (Unpublished study received Feb 9, 1977 under 15382-14; prepared by Food and Drug Research Laboratories, Inc., submitted by Kalo Laboratories, Inc., Kansas City, MO.; CDL:235651-D)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Formaldehyde/Paraformaldehyde Standard

MRID	CITATION
00082130	Horton, A.W.; Tye, R.; Stemmer, K.L. (1963) Experimental carcinogenesis of the lung: Inhalation of gaseous formaldehyde or an aerosol of coal tar by C3H mice. Journal of the National Cancer Institute 30(1):31-40. (Published study; CDL:095382-R)
00082132	Salem, H.; Cullumbine, H. (1960) Inhalation toxicities of some aldehydes. Toxicology and Applied Pharmacology 2:183-187. (Also in unpublished submission received Oct 15, 1973 under 4G1438; submitted by Chevron Chemical Co., Richmond, Calif.; CDL: 095382-T)
00082134	Coon, R.A.; Jones, R.A.; Jenkins, L.J., Jr.; et al. (1970) Animal inhalation studies on ammonia, ethylene glycol, formaldehyde, dimethylamine, and ethanol. Toxicology and Applied Pharmacology 16:646-655. (Also in unpublished submission received Oct 15, 1973 under 4G1438; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095380-W)
00082145	Mills, S.C.; Sharry, L.F.; Cook, L.J.; et al. (1972) Metabolism of 14C formaldehyde when fed to ruminants as an aldehyde-casein-oil complex. Australian Journal of Biological Science 25:807-816. (Also in unpublished submission received Oct 15, 1973 under 4G1438; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095383-L)
00082147	Chevron Chemical Company (19??) Metabolism of C14-Formaldehyde in Mice. (Unpublished study, including published data, received Oct 15, 1973 under 4G1438; CDL:095383-N)
00082153	Chevron Chemical Company (1972) Determination of Residues of Ortho 13,745 and Two of Its Metabolites in Corn: File No. 740.01. Method RM-15-2 dated Sep 15, 1972. (Unpublished study received Oct 15, 1973 under 4G1438; CDL:095383-U)
00096223	Marzulli, F.N.; Maibach, H.I. (1974) The use of graded concentrations in studying skin sensitizers: Experimental contact sensitization in man. Food and Cosmetics Toxicology 12(2):219-227. (Also in unpublished submission received Mar 3, 1975 under 100-491; submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL: 140055-Q)
00101857	Bentley, R. (1975) Acute Toxicity of Ten Baroid Compounds to Bluegill ... and Rainbow Trout (Salmo gairdneri). (Unpublished study received May 20, 1975 under 17664-8; prepared by Bionomics, EG & G, submitted by Baroid, Div. of N.L. Industries, Inc., Houston, TX; CDL:222885-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Formaldehyde/Paraformaldehyde Standard

MRID	CITATION
00117674	Davis, T.; Battista, S.; Kensler, C. (1965) Effect of Cigarette Smoke, Acrolein and Formaldehyde on Pulmonary Function. Taken from: Source unknown 24(2). (Abstract 2147; also in unpublished submission received Jun 17, 1976 under 201-118; submitted by Shell Chemical Co., Washington, DC; CDL:224738-A)
00119785	Arthur D. Little, Inc. (1966) Acute Toxicity of Mold-X in Rats, Rabbits and Guinea Pigs: C-68441. (Unpublished study received Sep 5, 1967 under 9870-1; submitted by Span Assoc., Inc., Oil City, PA; CDL:100671-A)
00122750	Fink, R.; Beavers, J.; Brown, R.; et al. (1981) Eight-day Dietary LC50--Bobwhite Quail: 10318001: MEHSL Study No. 2001-80. Final rept. (Unpublished study received Dec 20, 1982 under 359-708; prepared by Wildlife International Ltd. and Washington College, submitted by Rhone-Poulenc, Inc., Monmouth Junction, NJ; CDL: 071322-D)
00123774	Chevron Chemical Co. (1973) The Results of Tests on the Amount of Residue MBP Remaining, Including a Description of Analytical Methods Used. (Compilation; unpublished study received 1973 under 4G1438; CDL:093832-AL)
00124552	Phillips, L.; Steinberg, M.; Maibach, H.; et al. (1972) A comparison of rabbit and human skin response to certain irritants. Toxicology and Applied Pharmacology 21:369-382. (Also in unpublished submission received 1972 under 4G1438; submitted by Chevron Chemical Co., Richmond, CA; CDL:093832-P)
00124671	Koivusalo, M. (1956) Studies on the metabolism of methanol and formaldehyde in the animal organism. Acta Physiological Scandinavica 39(131):9-103. (Also in unpublished submission received Apr 15, 1974 under 4F1488; submitted by Celanese Chemical Co., Dallas, TX; CDL:094622-B)
00124672	Malorny, G.; Rietbrock, N.; Schneider, M. (1965) The Oxidation of Formaldehyde to Formic Acid in Blood: Investigation of the Metabolism of Formaldehyde. A translation of: Dic oxydation des formaldehyds zu ameisensaure im blut, ein beitrag zum stoffwechsel des formaldehyds. Naunyn-Schmiedebergs Arch. Exp. Path. U. Pharmak. 250:419-436. (Unpublished study received Apr 15, 1974 under 4F1488; submitted by Celanese Chemical Co., Dallas, TX; CDL:094622-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Formaldehyde/Paraformaldehyde Standard

MRID	CITATION
00124679	Celanese Chemical Co. (1973) Analtyical Methods: Formaldehyde. (Compilation; unpublished study received Apr 15, 1974 under 4F1488; CDL:094622-J)
00126394	Heitmuller, T. (1975) Acute Toxicity of Surflo-B17 to Larvae of the Eastern Oyster ..., Pink Shrimp ..., and Fiddler Crabs (Uca pugilator). (Unpublished study received Jul 15, 1975 under 17664-5; prepared by Bionomics--EG & G, Inc., submitted by Baroid Div., N.L. Industries, Inc., Houston, TX; CDL: 222880-A)
00126396	Heitmuller, T. (1975) Acute Toxicity of Surflow-B19 to Larvae of the Eastern Oyster ..., Pink Shrimp ..., and Fiddler Crabs (Uca pugilator). (Unpublished study received Jul 15, 1975 under 17664-15; prepared by Bionomics--EG & G, Inc., submitted by Baroid Div., N.L. Industries, Inc., Houston, TX; CDL: 222884-A)
00127059	Gainer, A. (1972) Results of Analyses: Rats--Rabbits: Lab No. A-4894. (Unpublished study received Jan 18, 1973 under 17664-5; prepared by Analytical and Testing Laboratories, submitted by Baroid, Div. of N.L. Industries, Inc., Houston, TX; CDL: 004622-B)
00127060	Baroid (1972) Surflo B19: Toxicity Study--Rats and Other Subjects. (Compilation; unpublished study received Jan 18, 1973 under 17664-15; CDL:004629-A)
00127069	Thomas R.; Murdock M. (1970) Subacute Studies--Chickens: Oral. (Unpublished study received Jun 30, 1970 under 9600-1; submitted by Delst Chemical & Research Co., Anaheim, CA; CDL:005886-A)
00127071	Thomas, R.; Murdock, M. (1970) Eye Toxicity--Rabbits: 2 Weeks. (Unpublished study received Jun 30, 1970 under 9600-1; submitted by Delst Chemical & Research Co., Anaheim, CA; CDL:005886-C)
00127500	Gainer, A. (1972) Results of Analyses: Surflo B-19L Rats, Rabbits: Lab No. A-4894. (Unpublished study received Jan 18, 1973 under 17664-15; prepared by Analytical and Testing Laboratories, submitted by Baroid Div., N.L. Industries, Inc., Houston, TX; CDL:237199-A)
00127503	Levenstein, I. (1979) LD50 Test: Rabbits: Green Liquid #2812: Assay No. 93445. (Unpublished study received Jan 23, 1979 under 2596-71; prepared by Leberco Laboratories, submitted by Hartz Mountain Corp., Harrison, NJ; CDL:237325-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Formaldehyde/Parafonmaldehyde Standard

MRID	CITATION
00128086	Heitmuller, T. (1975) Acute Toxicity of Surflo-B16 to Larvae of the Eastern Oyster ..., Pink Shrimp ..., and Fiddler Crabs (Uca pugilator). (Unpublished study received Jul 15, 1975 under 17664-9; prepared by Bionomics--EG & G, Inc., submitted by Baroid Div., N.L. Industries, Inc., Houston, TX; CDL: 222882-A)
00132485	Bills, T.; Marking, L.; Chandler, J. (1977) Formalin: Its toxicity to nontarget aquatic organisms, persistence, and counteraction. Pages 1-7, In U.S. Fish Wildl. Serv. Invest. Fish Control, 73. S.l.: s.n.. (Also in unpublished submission received Oct 26, 1983 under 44797-15; submitted by NL Treating Chemicals/NL Industries, Inc., Houston, TX; CDL:251681-A)
00132488	Henson, E. (1959) The toxicology of some aliphatic aldehydes. Journal of Occupational Medicine 1(Aug):457-462. (Also in unpublished submission received Oct 26, 1983 under 44797-15; submitted by NL Treating Chemicals/NL Industries, Inc., Houston, TX; CDL:251682-B)
00132490	Carpenter, C.; Smyth, H. (19??) Chemical burns of the rabbit cornea. Source unknown 29:1363-1372. (Also in unpublished submission received Oct 26, 1983 under 44797-15; submitted by NL Treating Chemicals/NL Industries, Inc., Houston, TX; CDL: 251682-E)
00132492	Auerbach, C.; Moutschen-Dahmen, M.; Moutschen, J. (1977) Genetic and cytogenetical effects of formaldehyde and related compounds. Mutation Research 39:317-347. (Also in unpublished submission received Oct 26, 1983 under 44797-15; submitted by NL Treating Chemicals/NL Industries, Inc., Houston, TX; CDL:251682-G)
00132494	Griesemer, R.; Ulsamer, A.; Arcos, J.; et al. (1982) Report of the Federal Panel on Formaldehyde. Environmental Health Perspectives 43(Feb):139-168. (Also in unpublished submission received Oct 26, 1983 under 44797-15; submitted by NL Treating Chemicals/ NL Industries, Inc., Houston, TX; CDL:251682-I)
00134117	Bryant, H. (1967) 971 Germicide Sterilized Vinyl Plastic (PVC); 971 Germicide Sterilized Rubber Material; Cidex Germicide Sterilized Plastic (PVC); Cidex Germicide Sterilized Rubber Material: Project HRC 929. (Unpublished study received Feb 27, 1968 under unknown admin. no.; submitted by ?; CDL:117595-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the Formaldehyde/Paraformaldehyde Standard

MRID	CITATION
00137247	Juhr, V.; Klomburg, S.; Haas, A. (1978) Trankwassersterilisation mit peressigsaure. Z. Versuchstierk. 20:65-72. (Also in unpublished submission received Jan 27, 1984 under 887-46; submitted by Bonewitz Chemical Services, Inc., Burlington, IA, CDL:252312-G)
00137297	Exxon Corp. (1973?) Formaldehyde: Toxicity in Animals. (Unpublished study received Jan 30, 1984 under IL 84/1; submitted by State of Illinois, Springfield, IL; CDL:252394-A)
00148770	N.L. Treating Chemical Co. (1985) Acute Toxicological Evaluations of Estuarine Organisms...Unpublished compilation prepared by EnviroSystems, Inc. in cooperation with Anatec Laboratories. 34 p.
00148772	Miller, P. (1985) Acute Toxicity of Formalin on Daphnia magna. Unpublished study prepared by N L. Treating Chemicals. 29 p.
00148773	Fletcher, D. (1983) 8-Day Dietary LC50 Study with Surflo-B315 in Bobwhite Quail: BLAL No. 83 QC 39. Unpublished study prepared by Bio-Life Associates. 17 p.
00148774	Fletcher, D. (1984) Acute Toxicity Study with Surflo-B315 in Bobwhite Quail: BLAL No. 83 QD 38. Unpublished study prepared by N.L. Treating Chemicals. 20 p.
00148775	Fletcher, D. (1983) 8-Day Dietary LC50 Study with Surflo-B315 in Mallard Ducklings: BLAL No. 83 DC 40. Unpublished study prepared by Bio-Life Associates, Ltd. 17 p.
GS0556-001	Committee on Toxicology (1980) Formaldehyde: An Assessment of Its Health Effects. Unpublished study prepared by Board on Toxicology and Environmental Health Hazards, National Research Council, National Academy of Sciences, under contract N000014-79-C-0049 to the Office of Naval Research. 45 p.

Form Approved. OMB No. 2070-0057. Approval expires 11-30-89.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

Form Approved. OMB No. 2070-0057. Expires 11-30-89.

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

OMB Approval No. 2070-0057 (Expires 11/30/89)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date _____ _____

Registration Standard for _____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: _____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of generic data on the active ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _____ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____ .

(4) My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product to one that is not registered and purchased.

(5) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(6) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: _____
(Signature)

Dated: _____ _____
(Typed)

EPA Form 8570-27