United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-R-94-027
September 1994

Reregistration Eligibility Decision (RED)

Sodium and Zinc Salts of 2-Mercaptobenzothiazole

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case 2380 which includes the active ingredients sodium 2-mercaptobenzothiazole and zinc 2-mercaptobenzothiazole. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses are due 90 days from the date of this letter. The second set of required responses are due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Franklin Gee at (703) 308-8008. Address any questions on required generic data to the Special Review and Reregistration Division representative Kathleen Depukat at 703-308-8587.

Sincerely yours,

Louis P. True, Jr., Acting Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, another DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific letter will be enclosed describing such data. Complete the two response forms provided with each DCI letter (or four forms for the combined) by following the instructions provided. **You must submit the response forms for each product and for each DCI within 90 days of the date of this letter (RED issuance date); otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for data waivers must be submitted as part of the 90-day response. Requests for time extensions should be submitted in the 90-day response, but certainly no later than the 8-month response date. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

SODIUM AND ZINC SALTS OF 2-MERCAPTOBENZOTHIAZOLE

LIST B

CASE 2380

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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SODIUM AND ZINC SALTS OF 2-MERCAPTOBENZOTHIAZOLE
REREGISTRATION ELIGIBILITY DECISION TEAM

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Phyllis Johnson	Biological Analysis Branch

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid equivalent
a.i.	Active Ingredient
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GRAS	Generally Recognized As Safe as designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	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, air or feed, e.g., mg/l, mg/kg or ppm.

GLOSSARY OF TERMS AND ABBREVIATIONS

LD_{50}	Median Lethal Dose. A statistically derived single dose that 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.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOEL	Lowest Observed Effect Level
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin Of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAM	Pesticide Analytical Method
ppm	Parts Per Million
PRN	Pesticide Registration Notice

GLOSSARY OF TERMS AND ABBREVIATIONS

Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RS	Registration Standard
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography

EXECUTIVE SUMMARY

The U. S. Environmental Protection Agency (referred to as "the Agency") has completed an assessment of the potential human health and environmental risks associated with the pesticide uses of the sodium and zinc salts of 2-mercaptobenzothiazole. The Agency has determined that pesticide products containing either of these chemicals as active ingredients, labeled and used as specified in this Reregistration Eligibility Decision document (RED) will not cause unreasonable risk to humans or the environment. Therefore, the Agency has concluded that products containing the sodium and zinc salts of 2-mercaptobenzothiazole are eligible for reregistration.

The sodium and zinc salts of 2-mercaptobenzothiazole are used as fungicides, microbiocides and bacteriostats. The end-use products are formulated as wettable powders, emulsifiable concentrates, and ready-to-use liquids for industrial use. These salts are used as preservatives for adhesives, latex/oil paints, paper products, metal working cutting fluids, and textile fibers. There are no registered food uses.

Toxicologically, the Agency classifies 2-mercaptobenzothiazole as a non-quantifiable "Group C" (possible human) carcinogen. The sodium salts are classified as Toxicity Category I, high toxicity, for skin and eye effects because their pH is greater than 10. The zinc salts are classified as Toxicity Category III, moderate to low acute toxicity, for acute skin and eye effects.

The metal working cutting fluid use of the sodium salt of 2-mercaptobenzothiazole is the only use pattern which has an effluent discharge into aquatic environments. The acute Level of Concern is exceeded for endangered aquatic organisms for this use pattern. As the sodium salt of 2-mercaptobenzothiazole will be discharged at a number of different sites, it is reasonable to assume that endangered species are located in some of these habitats. When the Agency completes its Endangered Species Program, additional precautionary labeling may be required to mitigate the risk to endangered aquatic species. Also, the Agency has required a hydrolysis study on the technical grade of sodium 2-mercaptobenzothiazole for the reregistration of the salts of 2-mercaptobenzothiazole. Hydrolysis data were required to help confirm the environmental assessment.

Before reregistering the products containing the sodium and zinc salts of 2-mercaptobenzothiazole, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the Agency of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredients are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration 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" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of the sodium and zinc salts of 2-mercaptobenzothiazole. The document consists of six sections. Section I is the introduction. Section II describes the salts of 2-mercaptobenzothiazole, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for the sodium and zinc salts of 2-mercaptobenzothiazole. Section V discusses the reregistration requirements for the sodium and zinc salts of 2-mercaptobenzothiazole. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredients are covered by this Reregistration Eligibility Decision:

1. Sodium 2-Mercaptobenzothiazole

- **Common Name:** 2-Mercaptobenzothiazole, sodium salt
- **Chemical Name:** Sodium 2-Mercaptobenzothiazole
- **OPP Chemical Code:** 051704
- **CAS Registry Number:** 2492-26-4
- **Empirical Formula:** $C_7H_4NS_2Na$

2. Zinc 2-Mercaptobenzothiazole

- **Common Name:** 2-Mercaptobenzothiazole, zinc salt
- **Chemical Name:** Zinc 2-Mercaptobenzothiazole
- **OPP Chemical Code:** 051705
- **CAS Registry Number:** 155-04-4
- **Empirical Formula:** $C_{14}H_8N_2S_4Zn$

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these uses of the salts of 2-mercaptobenzothiazole is in Appendix A.

For **2-Mercaptobenzothiazole, sodium salt**:

Type of Pesticide: Bacteriostat, Fungicide, Microbiocide/Microbiostat (slime-forming bacteria and fungi) - Preservatives/Industrial Preservatives.

Use Sites:

INDOOR NON-FOOD: Emulsions, Resin/Latex/Polymer
Metal Working Cutting Fluids
Paper/Paper Products
Specialty Industrial Products
Textiles/Textile Fibers/Cordage
Wet-End Additives/Industrial Processing Chemicals

INDOOR RESIDENTIAL: Wood Protection Treatment to Buildings/Products Indoor

Target Pests: Mold, mildew, and bacteria and fungi which cause degradation of aqueous industrial products.

Formulation Types Registered:

TYPE: End Use

FORM: Soluble Concentrate/Liquid

Method and Rates of Application:

Types of Treatment: Preservative/industrial preservative for metal working cutting fluids, emulsions, hydroxyethyl cellulose solutions, protective colloids, waxes, polishes, starch paste, alginate paste, and casein solutions - industrial preservative treatment, preservative treatment - 5 to 240 ppm.

Industrial preservative of paper and paper products (non-food contact) 396 to 792 ppm.

Preservative of cotton fabric - adding treatment - 1263 ppm.

Mold protection of wood veneer - dip - 120 ppm.

Equipment - Measuring container, metering pump, and not specified.

Method and Rate - See Types of Treatment.

Timing - During manufacture, not specified.

Use Practice Limitations:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. Preservative treatment of metal working cutting fluids would be periodically repeated at not greater than 5-week intervals. Do not use for the manufacture of mold-resistant paper and paperboard intended for food packaging purposes.

For **2-Mercaptobenzothiazole, zinc salt**:

Type of Pesticide: Bacteriostat, Fungicide, Microbiocide/Microbiostat (slime-forming bacteria and fungi).

Use Sites:

INDOOR NON-FOOD:	Adhesives, Industrial Coatings, Industrial Paints, Latex/Oil/Varnish (Applied Film) Paper/Paper Products Textiles/Textile Fibers/Cordage

Target Pests: Mold, mildew, bacteria and fungi which cause degradation of aqueous industrial products, fabrics, and yarns; slime-forming bacteria and fungi in industrial water systems.

Formulation Types Registered:

TYPE:	End Use
FORM:	Soluble Concentrate/Liquid, Wettable Powder

Method and Rates of Application:

Equipment -	Calender, press, metering pump and not specified.
Method and Rate -	Preservative/industrial preservative for starch and protein adhesive dispersions, and paper coatings - industrial preservative treatment, preservative treatment - 75 to 200 ppm active ingredient. Preservative/industrial preservative for latex paint -industrial preservative treatment, preservative treatment - 625 to 2250 ppm active ingredient. Industrial preservative of paper and paper products (non-food contact) - 400 ppm active ingredient. Preservative of industrial yarns and fabric - preservative treatment - 750 to 1200 ppm active ingredient.

Timing -	During manufacture, continuous feed, initial, intermittent, subsequent/maintenance.
Use Practice Limitations:	
	Do not use for the manufacture of mold-resistant paper and paperboard intended for food packaging purposes. Do not use in formulation containing metallic dryer. Preclean for heavily soiled areas.

C. Data Requirements

Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

D. Regulatory History

Sodium 2-mercaptobenzothiazole was registered in the United States as early as 1949 to R. T. Vanderbilt Company, Inc. as an active ingredient in an industrial preservative product. Currently, only one product is registered for use in wood and paper/paperboard treatment and as a preservative in metal working cutting fluids, emulsions, textiles and pastes.

Zinc 2-mercaptobenzothiazole was registered in the United States as early as 1955 to R. T. Vanderbilt Company, Inc. as an active ingredient in an industrial preservative product. Currently, two products are registered for use as a preservative in adhesives, textiles, paints, coatings, and paper products.

Data Call-In Notices were issued in 1991 to acquire additional generic data including product chemistry, ecotoxicity and toxicology data for reregistration for these two active ingredients.

2-Mercaptobenzothiazole was registered in the United States as early as 1956 to Betz Laboratories as an active ingredient. Currently, there are no registered products; all the products have been cancelled.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

The data submitted pertaining to the physical and chemical characteristics of sodium 2-mercaptobenzothiazole and zinc 2-mercaptobenzothiazole are adequate and summarized below in Table 1.

Table 1.

Characteristic	AI 051704 Sodium 2-MBT	AI 051705 Zinc 2-MBT
Color	Solid - pale yellow to yellow Liquid - deep yellow to dark brown	Pale yellow to yellow
Physical State	Solid	Solid
Odor	Mercaptan-sulfur smell	Sulfur like
Melting Point	159.81° C to 180.38° C	178.47° C
Density	1.47 g/cm^3	1.73 g/cm^3
Solubility	Water 100% Isopropanol 7.10 g/100 ml DMF 6.00 g/100 ml Acetone 1.60 g/100 ml Insoluble in Xylene	Insoluble in Water Isopropanol 0.84 g/100 ml DMF 9.96 g/100 ml Acetone 5.52 g/100 ml Xylene 1.00 g/100 ml
Vapor Pressure	24 mm HG at 25°C	0.9 mm Hg at 22.5°C
Dissociation Constant	Pk_a = 11.6 for 50% solution	Complete ionization is expected
Octanol/Water Partition Coefficient	K_{ow} = 0.64 at 25°C	K_{ow} = 11.4 at 25°C
pH	10 for 1% solution > 11.5 for 50% aqueous material	5.55 for 1% suspension in water

Characteristic	AI 051704 Sodium 2-MBT	AI 051705 Zinc 2-MBT
Stability	Stable in liquid form in the alkaline medium. Precipitates out in presence of acids or heavy metals. Solid form is stable in sealed moisture proof container. Material is hygroscopic and vulnerable to oxidation.	2.06% loss at 284°C; degradation is faster above 284°C
Oxidizing/Reducing Reaction	It is a reducing agent.	It is a reducing agent.

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data bases for the sodium and zinc salts of 2-mercaptobenzothiazole are adequate to support reregistration. While the Agency required only data on acute, developmental, and subchronic toxicology and mutagenicity because of these pesticides' use patterns, data from other studies were available. These data are summarized below.

a. Acute Toxicity

The acute toxicity data on the salts of 2-mercaptobenzothiazole are summarized in Table 2. Based on a pH of 11.5 for the sodium salt, the acute dermal toxicity, primary eye irritation, primary dermal and dermal sensitization studies were waived. This high pH value places the sodium salt of 2-mercaptobenzothiazole in Toxicity Category I for dermal toxicity, eye irritation, and skin irritation. The acute inhalation toxicity studies for both salts were not required because under the directions of use, the active ingredient and/or the end-use products, will not result in an inhalative material.

Table 2.

Summary of Acute Toxicity Data on Sodium and Zinc 2-Mercaptobenzothiazole			
Guideline	Description	Test Results	Toxicity Category
81-1	Oral LD_{50} - rat (Sodium salt)	1476 mg/kg (M&F) 1615 mg/kg (M) 1337 mg/kg (F)	III
81-1	Oral LD_{50} - rat (Zinc salt)	5505 mg/kg (M&F) 5735 mg/kg (M) 5221 mg/kg (F)	IV
81-2	Dermal LD_{50} - rabbit (Zinc salt)	> 2000 mg/kg	III
81-4	Primary Eye Irritation - rabbit (Zinc salt)	Minimal Irritant	III
81-5	Primary Skin Irritation - rabbit (Zinc salt)	Slight Dermal Irritant	IV
81-6	Dermal Sensitization - guinea pig (Zinc salt)	No Sensitization	N/A

In an acute oral study in Sprague-Dawley rats of sodium 2-mercaptobenzothiazole, the LD_{50} was 1476 mg/kg for the combined sexes, 1615 mg/kg for males and 1337 mg/kg for females (MRID 41567201). In an acute oral study in Sprague-Dawley rats of zinc 2-mercaptobenzothiazole, the LD_{50} was 5505 mg/kg for the combined sexes, 5735 mg/kg for males and 5221 mg/kg for females (MRID 41571901). In an acute dermal toxicity study in New Zealand White Rabbits, the LD_{50} was > 2000 mg/kg (MRID 41571902). In a primary eye irritation study, the application of 74.06% zinc 2-mercaptobenzothiazole in the eyes of New Zealand White Rabbits caused conjunctival redness, chemosis, and discharge (MRID 41571903). In a dermal irritation study, 0.5 grams of zinc 2-mercaptobenzothiazole in New Zealand White Rabbits caused a slight dermal irritation in one of three rabbits. No other dermal irritation was observed (MRID 41571904). In a dermal sensitization study with Hartley guinea pigs,

zinc 2-mercaptobenzothiazole did not elicit a sensitization response (MRID 41571905).

b. Subchronic Toxicity

A 13-week dermal toxicity study with sodium 2-mercaptobenzothiazole was conducted with Sprague Dawley rats. Doses of 0, 200, 1000, or 2000 mg/kg/day were applied daily for 91 days. The NOEL was 200 mg/kg/day. The LOEL was 1000 mg/kg/day, based on statistically significant increased relative liver weights in 1000 and 2000 mg/kg/day females. No other adverse effects due to treatment were found (MRID 42146301).

c. Chronic Toxicity and Carcinogenicity

In a carcinogenicity study conducted by NTP, F344/N rats were dosed with 2-mercaptobenzothiazole by gavage for 103 weeks. The animals were dosed 5 days/week at 0, 375, or 750 mg/kg for males and 0, 188, or 375 mg/kg for females. There were increased incidences of pituitary adenomas/adenocarcinomas and of adrenal gland pheochromocytomas in the dosed females and increased incidences of adrenal gland pheochromocytomas/malignant pheochromocytomas and of preputial gland adenomas/carcinomas in the dosed males. Increased incidences of mononuclear cell leukemia and pancreatic acinar cell adenomas were also present in low dose males. Inflammation and ulceration of the forestomach occurred in all dosed rats, and there was increased mortality in dosed males (Dieter, 1988).

NTP also tested 2-mercaptobenzothiazole for carcinogenicity in B6C3F1 mice. Doses of 0, 375, or 750 mg/kg were given by gavage on five days per week for 103 weeks. There appeared to be an increased incidence of hepatocellular adenomas and carcinomas in the low dose females, but not in the high dose females or in the male mice. Mortality was high in the high dose females. Of the mice that died early, most had lung hemorrhage and congestion (Dieter, 1988).

2-Mercaptobenzothiazole has been classified as a Group C possible human carcinogen. There was some evidence of adrenal gland tumors in male and female rats and some evidence of preputial gland tumors in male rats. Other tumor evidence was considered equivocal (Dapson and Rinde, 1992).

d. Developmental Toxicity

2-Mercaptobenzothiazole was given to Sprague Dawley rats by gavage on gestation days 6 through 15 in a developmental toxicity study. The doses were 0, 300, 1200, or 1800 mg/kg/day. The NOEL for maternal toxicity was 300 mg/kg/day. The LOEL was 1200 mg/kg/day, based on hair loss, increased salivation, and urine staining at the two higher doses. The high dose animals also showed reduced body weight gain and food consumption. The NOEL for developmental toxicity was 1200 mg/kg/day, and the LOEL was 1800 mg/kg/day, with greater post implantation loss (MRID 41422202).

e. Reproductive Toxicity

In a two-generation reproduction study, Crl:CD COBS BR rats were fed 2-mercaptobenzothiazole at 0, 2500, 8750, or 15000 ppm in the diet (0, 194, 695, or 1195 mg/kg/day for males and 0, 218, 783, or 1327 mg/kg/day for females). The reproductive/systemic NOEL was 2500 ppm, a threshold NOEL based on a slight decrease in body weight at this dose. The LOEL was 8750 ppm, based on decreased body weight at the two higher doses, as well as liver toxicity and increased kidney weights with increased brown pigment in the kidneys. Males at the two higher doses also had increased incidence of basophilic tubules in the kidney cortex (MRID 41912501).

f. Mutagenicity

2-Mercaptobenzothiazole was evaluated in the Ames *Salmonella typhimurium*/mammalian microsome assay and was nonmutagenic in strains TA1535, TA1537, TA100, TA1538, and TA98, with and without activation (MRID 41045601). This compound did not induce mutations at the HGPRT locus in Chinese hamster ovary cells (MRID 41045602). However, 2-mercaptobenzothiazole did cause forward gene mutation in mouse lymphoma cells, with and without activation (MRID 41045603). This test substance was negative in an *in vivo* mouse micronucleus assay (MRID 41045604). 2-Mercaptobenzothiazole did not induce unscheduled DNA synthesis in rat primary hepatocytes (MRID 41525501).

g. Metabolism and Dermal Absorption

Male and female Fischer 344 rats were dosed orally with separate single doses (one high and one low dose) of radiolabeled 2-mercaptobenzothiazole and of radiolabeled 2-mercaptobenzothiazole

disulfide. Both compounds appeared to be absorbed readily and excreted in a similar manner, mainly via the urine. About 50% was excreted in urine within 8 hours. Measurable amounts of label were found in feces, whole blood and plasma. The data demonstrate absorption and binding of both substances following oral exposure.

Single dermal doses of these same two compounds were applied to male and female Fischer 344 rats and to female Hartley guinea pigs. Both compounds were absorbed through the skin, with the main route of excretion via the urine. The majority of the dose remained on the skin and was only partly removed by washing. Thus, there was potential for continued absorption and local dermal toxicity. Based on these data, it is assumed that dermal absorption may be 38% of the dose. (MRIDs 41123401, 41123402, 41123403).

h. Reference Dose (RfD) for Chronic Oral Exposure

Although these pesticides are not currently registered for food uses, the RfD for 2-mercaptobenzothiazole was determined to be 0.65 mg/kg/day based on results of the rat reproductive toxicity study described above. The NOEL was 194 mg/kg/day (2500 ppm) for reproductive and systemic effects. An uncertainty factor of 100 was used to account for inter-species extrapolation and intra-species variability, with an additional factor of three to account for the lack of chronic toxicity data in a non-rodent species.

2. Exposure Assessment

a. Dietary

A food additive tolerance has been established for 2-mercaptobenzothiazole in food grade adhesives (see 21 CFR 175.105). Current labeling allows the adhesive use only for products containing the zinc salt. This area is under the jurisdiction of the U.S. Food and Drug Administration and is not directly regulated by EPA.

A tolerance also exists for the use of 2-mercaptobenzothiazole in food grade paper and paperboard (see 21 CFR 176.300). However, current labeling for the products containing the zinc and sodium salts of 2-mercaptobenzothiazole restrict the use to non-food materials in paper and paperboard manufacture.

b. Occupational and Residential

For products containing sodium or zinc 2-mercaptobenzothiazole, application methods such as open pouring of the liquid concentrate, and open pouring of the powder into adhesives, paints, and other industrial products present the potential for dermal and inhalation exposure to applicators. Dermal exposure would be the primary route of exposure. Therefore, the Agency required an applicator dermal exposure study.

The registrant is a participant in the Chemical Manufacturers Association (CMA) Antimicrobial Exposure Assessment Study (MRID 41412201). The study fulfills the data requirement for an applicator/mixer/loader exposure study. An exposure and risk assessment for applicator/mixer/loaders has been done based on that study. All exposure estimates in the CMA study reflect typical work practice during the industrial use of the biocide. The estimates represent combined dermal and inhalation exposure.

To estimate potential exposure to applicators/mixers/loaders from sodium or zinc 2-mercaptobenzothiazole products, the Agency used the end-use product, Vancide 51, containing 2.4% of sodium 2-mercaptobenzothiazole as the active ingredient, to represent exposure for both sodium and zinc 2-mercaptobenzothiazole. Vancide 51 is added as (1) a preservative for paste by adding 1.0% Vancide 51 to the starch paste based on the weight of the starch; and (2) for metal working cutting fluids.

Table 3.

POUR LIQUID				
Setting	MCS* (ug/lb ai)	lb ai/ used	BW** (kg)	Daily Exp. (ug/kg/day)
Preservative	130	2.25	70	4.18
Metal Working Cutting Fluid	100	0.23	70	0.33

* MCS = Maximum Credible Sum was derived from CMA Study.
** BW = Body Weight
Daily Exposure (ug/kg/day) = (MCS X lb ai/used) / BW

Post-application exposure from the treated paint, adhesives, textiles and other treated industrial products are not considered significant because of the low concentration/dilution factor as compared to the exposure to the applicators, mixers, and loaders. There will be low potential for any significant residential exposure from these uses.

3. Risk Assessment

a. Occupational and Residential

2-Mercaptobenzothiazole was classified as carcinogenicity Category C (possible human carcinogen; non-quantifiable). While a linear, multi-stage model for carcinogenicity risk assessment was not appropriate because the uses of the pesticide products are not likely to result in repeated human exposure, over a significant portion of the human life span, margins of exposure (MOEs) were calculated to quantify the risk to applicators/mixers/loaders. The Agency conducted an assessment to estimate the short and intermediate risk from sodium 2-mercaptobenzothiazole to applicators/mixers/loaders for the preservative and metal working cutting fluid uses. For the occupational risk assessment the NOEL is 200 mg/kg/day based upon an increase in the liver weights of female rats treated with higher doses. It also used the calculated daily exposure estimates above. The calculated MOEs appear below in Table 3.

Margin of Exposure (MOE) = NOEL/Daily Exposure

For example, the MOE calculation for the preservative use is:

$$\text{MOE} = \frac{200 \text{ mg/kg/day} \times 1000 \text{ µg/mg}}{4.18 \text{ µg/kg/day}} = 47{,}000$$

Table 4.

Risk Calculation		
Setting	Daily Exposure (ug/kg/day)	MOE
Preservative	4.18	47,000
Metal Working Cutting Fluid	0.33	600,000

The MOE is a measure of how closely the high end exposure approaches the NOEL (the highest dose at which no effects were observed in the laboratory test). In general, an MOE over 100 does not trigger a risk concern. As can be seen by the data presented in Table 3, the MOEs for the preservative and metal working cutting fluid uses of zinc and sodium salt of 2-mercaptobenzothiazole exceed 100 by several orders of magnitude. Therefore, additional toxicology or exposure studies were not required.

C. Environmental Assessment

1. Environmental Fate

a. Environmental Fate Assessment

A hydrolysis study is required for industrial use pesticides in which effluent is potentially discharged into aquatic environments. While the Agency has required this study on sodium 2-mercaptobenzothiazole to be submitted based on the use pattern and the results of the environmental exposure model discussed below, major environmental exposure to the sodium and zinc salts of 2-mercaptobenzothiazole is not expected. The Agency will use the hydrolysis data to confirm this assessment by determining the degradation rate of the active ingredient and products formed during hydrolysis.

2. Ecological Effects

Sufficient ecotoxicological data have been submitted to characterize the toxicity of the sodium and zinc salts of 2-mercaptobenzothiazole to nontarget terrestrial and aquatic organisms.

a. Ecological Effects Data

(1) Terrestrial Data - Avian

Avian studies conducted with the technical grade of 2-mercaptobenzothiazole indicate that this chemical is practically nontoxic (LD_{50} > 2150 mg/kg) to birds on an acute oral basis (MRID 42267101) and slightly toxic (LC_{50} > 3387 ppm) on a dietary basis (MRID 42428501).

(2) Aquatic Data

Aquatic studies conducted with the technical grade of 2-mercaptobenzothiazole indicate that it is highly toxic to freshwater fish (LC_{50} of 0.73 ppm for rainbow trout) (MRID 42233201) and moderately toxic to freshwater invertebrates (EC_{50} of 2.9 ppm for *Daphnia magna*) (MRID 42226001).

b. Ecological Effects Risk Assessment

As summarized above, sufficient information exists to establish that 2-mercaptobenzothiazole is practically nontoxic to birds on an acute oral basis and slightly toxic to birds on a dietary basis. The results of other toxicity studies indicate that 2-mercaptobenzothiazole may be highly toxic to freshwater fish (Rainbow trout LC_{50} = 0.73 ppm) and moderately toxic to aquatic invertebrates (*Daphnia* EC_{50} = 2.9 ppm). The use patterns of these chemicals except for sodium 2-mercaptobenzothiazole's use in metal working cutting fluids, suggest sodium and zinc 2-mercaptobenzothiazole would not pose adverse risks to avian and aquatic species.

Unlike agricultural pesticides in which aquatic organisms can be exposed to pesticides via runoff and drift, nontarget aquatic organisms are expected to be exposed to industrial microbiocides through a point source discharge. In the case of 2-mercaptobenzothiazole, the metal working cutting fluids use of the sodium salt is the only use pattern which has an effluent discharge into aquatic environments and, therefore, poses potential exposure to nontarget aquatic organisms.

To aid in the aquatic risk assessment of 2-mercaptobenzothiazole, the Agency used a screening model to assess the estimated environmental concentration of residue levels of this chemical in the receiving stream from the metal working cutting fluid use.

The screening model, a Tier Ic EEC (estimated environmental concentration), determines the maximum concentration that occurs immediately downstream from an industrial (point source) discharge site. These calculated EECs are those for a high exposure site with a return frequency of 1 in 10 years. The high exposure site represents a site that would be expected to produce larger EECs than 90% of all sites with the specified use pattern. A one-in-ten year EEC has a 10% probability of being equaled or exceeded in any single year at a given site or would be equaled or exceeded once every ten years at that site on a long term average. This is similar to the site and frequency assumptions that are generally being used for agricultural pesticides. EECs for a 50% (typical) site at mean stream flow were also calculated for the metal working cutting fluid use pattern.

Table 5.

Tier Ic EECs (ppm) for Sodium 2-Mercaptobenzothiazole		
Type of Use Site	Typical Exposure Scenarios	High Exposure Scenarios
Metal Working Cutting Fluids	0.0051	6.400

An acute Level of Concern (LOC) is exceeded when the EEC value equals or exceeds 1/2 the LC_{50} values for aquatic organisms. A chronic LOC is exceeded when the EEC value of the exposure model equals or exceeds 1/100 the acute LC_{50} values for aquatic organisms.

As can be seen from Table 5 below, the acute and chronic LOC values for freshwater fish and invertebrates are greater than the typical exposure scenario EEC values . Therefore, if the receiving streams never have a flow rate below their mean flow condition, there is minimal risk to freshwater aquatic organisms in these waters under those conditions.

However, for the high exposure scenario, a high acute and chronic risk to freshwater aquatic organisms is indicated.

Table 6.

Median Lethal Concentration Values (ppm) For Aquatic Organisms Exposed to Sodium 2-Mercaptobenzothiazole for the Metal Working Cutting Fluids Use Pattern		
Category	Freshwater Fish	Freshwater Invertebrates
LC_{50}	0.73	2.9
1/2 LC_{50} (Acute LOC)	0.365	1.45
1/20 LC_{50} (En. Sp. LOC)	0.146	0.58
1/100 LC_{50} (Chronic LOC)	0.0073	0.029

The LOC for endangered aquatic species is exceeded when the estimated EEC value equals or exceeds 1/20 the LC_{50} values. The high exposure scenario for 2-mercaptobenzothiazole exceeds the LOC for endangered freshwater fish and invertebrate species. As sodium 2-mercaptobenzothiazole will be discharged at a number of different sites, it is reasonable to assume that endangered species are located in some of these aquatic habitats. Effluent containing sodium 2-mercaptobenzothiazole should not be discharged into streams and other waterways where endangered aquatic organisms are known to reside.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing the sodium and zinc salts of 2-mercaptobenzothiazole active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing the sodium and zinc salts of 2-mercaptobenzothiazole. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of the sodium and zinc salts of 2-mercaptobenzothiazole, and lists the submitted studies that the

Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of the sodium and zinc salts of 2-mercaptobenzothiazole and to determine that these salts of 2-mercaptobenzothiazole can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing the sodium and zinc salts of 2-mercaptobenzothiazole as the sole active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data and the data identified in Appendix B. Although the Agency has found that all uses of the sodium and zinc salts of 2-mercaptobenzothiazole are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing these active ingredients, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredients, the Agency has sufficient information on the health effects of the sodium and zinc salts of 2-mercaptobenzothiazole and on its potential for causing adverse effects in fish, wildlife and the environment. Therefore, the Agency concludes that products containing these salts of 2-mercaptobenzothiazole for all uses are eligible for reregistration when the Agency has determined that the other active ingredients in those products are also eligible for reregistration.

The Agency has determined that the sodium and zinc salts of 2-mercaptobenzothiazole products, labeled and used as specified in this Reregistration Eligibility Decision document, will not pose unreasonable risks or adverse effects to humans or the environment.

2. Eligible Uses

The Agency has determined that all uses of the sodium and zinc salts of 2-mercaptobenzothiazole are eligible for reregistration.

B. Regulatory Position

The following is a summary of the regulatory positions and rationales for the sodium and zinc salts of 2-mercaptobenzothiazole. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

A food additive tolerance has been established for 2-mercaptobenzothiazole in food grade adhesives (see 21 CFR 175.105). Current labeling allows the adhesive use only for products containing the zinc salt. This area is under the jurisdiction of the U.S. Food and Drug Administration and is not directly regulated by EPA.

A tolerance also exists for the use of 2-mercaptobenzothiazole in food grade paper and paperboard (see 21 CFR 176.300). However, current labeling for the products containing the zinc and sodium salts of 2-mercaptobenzothiazole restrict the use to non-food materials in paper and paperboard manufacture.

2. Effluent Discharge/Aquatic Risk Rationale

The Agency has determined that discharge to surface waters of effluent containing sodium 2-mercaptobenzothiazole may result from its use as a pesticide. Its use as a pesticide and its potential release to the environment subjects it to the requirements of both FIFRA and the National Pollutant Discharge Elimination system (NPDES) which is administered by the EPA's Office of Water (OW) with the states.

By their nature, industrial biocides are often toxic to aquatic organisms. This is evident from the ecotoxicology data presented in the Science Assessment presented above. The effect to the environment of discharges containing biocides depends heavily upon the volume, concentration, and other constituents of a particular discharge, as well as such features as the size, nature, and flow rate of waters receiving the discharge. The preliminary estimate of environmental concentrations for sodium 2-mercaptobenzothiazole indicated that under typical exposure conditions this biocide did not meet or exceed the Agency's Levels of Concern (LOCs) for aquatic organisms. However, LOCs were exceeded for sodium 2-mercaptobenzothiazole under the high exposure modeling scenario.

FIFRA permits EPA to require the generation of data on the effects of biocides and to set general limits and conditions of use of a biocide through

statements on its labeling. However, these mechanisms do not readily provide for adaptation to varied and changing local conditions. Consequently, generalized regulation of a pesticide under FIFRA could inadequately restrict pesticide use under some local conditions. The NPDES process is designed to take local conditions into account through the issuance of permits for the discharge of pollutants to bodies of water. However, historically, specific information about the toxicological and environmental properties of biocides in effluent streams was not always readily available or considered in writing permits.

EPA's Office of Pesticide Programs and Office of Water intend to cooperate in the oversight of biocide uses to better employ the advantages offered by each program while avoiding unnecessary overlap in regulation. Under FIFRA, OPP will require the generation and submission to the Agency of information that will be used by OPP to identify extraordinary hazards that could affect national registration of biocide products use. Current information and that gathered in the future will be shared with the Office of Water where it can be made available to NPDES permit writers in addressing local aquatic effects of biocide use. In addition, OW will alert OPP to any additional information that becomes available concerning unanticipated aquatic effects of the use of this biocide for OPP's use in national registration decisions for these products. This approach should provide sufficient environmental safeguards while avoiding redundant effort since it allows OPP to control the general approval of the biocide as required by FIFRA, but includes a mechanism for recognizing and dealing with potential unacceptable effects on a local level through the NPDES program. Improved limitations on use under FIFRA and more accurate NPDES permitting decisions and accompanying permit limits for industrial biocides may be developed in the future as the information gathering and exchange program between the Offices progresses.

The Agency believes that the above process, coupled with the Agency's finding that the use of sodium 2-mercaptobenzothiazole does not raise extraordinary concerns about adverse effects from its potential discharge to surface waters, adequately addresses the test for reregistration of a pesticide under FIFRA -- "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." Therefore, despite some concerns about potential effects to aquatic organisms exposed to the effluent resulting from its use, the Agency has concluded that unreasonable adverse effects from the uses of sodium 2-mercaptobenzothiazole involving discharge to water are generally unlikely under the condition that an effluent discharge label statement (recognizing that any such discharge is subject to the NPDES process) is required for all products which have a potential for discharge to surface waters.

3. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered aquatic species to the sodium and zinc salts of 2-mercaptobenzothiazole as discussed above in the science assessment chapters.

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use modifications or a generic product label statement requiring users to consult county-specific bulletins. These bulletins would provide information about specific use restrictions to protect endangered and threatened species in the county. Consultations with the Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses.

The Agency plans to publish a description of the Endangered Species Program in the Federal Register in 1994 and by 1995 have enforceable county-specific bulletins available. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

Sodium 2-mercaptobenzothiazole's metal working cutting fluid use pattern may result in an effluent discharge into aquatic environments, and therefore, has potential exposure to nontarget aquatic organisms. The LOC for endangered aquatic organisms is exceeded for this use pattern. Effluent containing sodium 2-mercaptobenzothiazole should not be discharged into streams and other waterways where endangered aquatic organisms are known to reside.

4. Personal Protective Equipment (PPE) for Handlers (Mixer/Loader/Applicators)

For each end-use product, PPE requirements for pesticide handlers will be set during reregistration in one of two ways:

- If the Agency has no special concerns about the acute or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product.
- If the Agency has special concerns about an active ingredient due to very high acute toxicity or to certain other adverse effects,

such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, the Agency may establish minimum or "baseline" handler PPE requirements that pertain to all or most occupational end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of each end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

The Agency has determined that use of these pesticides is not likely to result in repeated human exposure over a significant portion of the human life span. Therefore, the establishment of active ingredient based PPE requirements are not warranted at this time. The PPE for pesticide handlers will be based on the acute toxicity of the end-use product.

5. Entry Restrictions for Occupational-Use Products (NonWPS Uses)

Exposure to sodium and zinc 2-mercaptobenzothiazole treated products, such as latex and oil paints, adhesives, paper products, and metal working cutting fluids, is expected to occur. However, the Agency has determined that since the exposure to the sodium and zinc salts of 2-mercaptobenzothiazole is negligible, as diluted in the treated products, such exposures do not warrant special restrictions.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of the salts of 2-mercaptobenzothiazole for the above eligible uses is substantially complete. A hydrolysis study has been required to confirm the environmental assessment by determining the degradation rate of sodium 2-mercaptobenzothiazole and

products formed during hydrolysis, as discussed above in Section III.C.1.a.

2. Labeling Requirements for Manufacturing-Use Products

Effluent Discharge Labeling Statements

Future manufacturing-use products containing sodium or zinc 2-mercaptobenzothiazole that may be contained in an effluent discharged to the waters of the United States or municipal sewer systems must bear the following revised effluent discharge labeling statement.

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

All affected products distributed or sold by registrants and distributors (supplemental registrants) must bear the above labeling by October 1, 1995. All products distributed or sold by persons other than registrants or supplemental registrants after October 1, 1997 must bear the correct labeling. Refer to PR Notice 93-10 or 40 CFR 152.46(a)(1) for additional information.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice. These products include product chemistry for each registration and acute toxicity testing.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix G; Attachment 5) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

Effluent Discharge Labeling Statements

Refer to subsection A. above for labeling requirements for effluent discharge for the metal working cutting fluid use of sodium 2-mercaptobenzothiazole only.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell sodium and zinc 2-mercaptobenzothiazole products bearing old labels/labeling, i.e., labels absent the modifications specified in this RED document, except as noted below, for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to your products.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)		Max. Appl. Rate (AI unless noted otherwise)		Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
EMULSIONS, RESIN/LATEX/POLYMER							Use Group: INDOOR NON-FOOD						
Industrial preservative treatment., During manufacture., Measuring container., Not Applicable., Not applicable for this use.	SC/L	W	40	W	160	*	NS	NS	NS	NS			
Industrial preservative treatment., During manufacture., Metering pump., Not Applicable., Not applicable for this use.	SC/L	W	40	W	160	*	NS	NS	NS	NS			
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	V	10	V	21	*	NS	NS	NS	NS			C18, C24
METALWORKING CUTTING FLUIDS							Use Group: INDOOR NON-FOOD						
Preservative treatment., Not on label., Measuring container., Not Applicable., Not applicable for this use.	SC/L	W	24	W	160	*	NS	NS	NS	NS			
Preservative treatment., Not on label., Metering pump., Not Applicable., Not applicable for this use.	SC/L	W	24	W	160	*	NS	NS	NS	NS			
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	V	10	V	21	*	NS	NS	NS	NS			C18, C24
PAPER/PAPER PRODUCTS							Use Group: INDOOR NON-FOOD						
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W	396	W	792	*	NS	NS	NS	NS			C18, C24
SPECIALITY INDUSTRIAL PRODUCTS							Use Group: INDOOR NON-FOOD						
Industrial preservative treatment., During manufacture., Measuring container., Not Applicable., Not applicable for this use.	SC/L	W	40	W	160	*	NS	NS	NS	NS			
Industrial preservative treatment., During manufacture., Metering pump., Not Applicable., Not applicable for this use.	SC/L	W	40	W	160	*	NS	NS	NS	NS			

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION											
NON-FOOD/NON-FEED (con't)											
TEXTILES/TEXTILE FIBERS/CORDAGE				Use Group: INDOOR NON-FOOD							
Padding treatment., Not on label., Not on label., Porous., Not applicable for this use.	SC/L	V 1263	V 1263	*	NS	NS	NS	NS			C18, C24
WET-END ADDITIVES/INDUSTRIAL PROCESSING CHEMICALS				Use Group: INDOOR NON-FOOD							
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W 5	W 240	*	NS	NS	NS	NS			C18, C24
WOOD PROTECTION TREATMENT TO BUILDINGS/PRODUCTS INDOOR				Use Group: INDOOR RESIDENTIAL							
Dip., Not on label., Not on label.	SC/L	V 120	V 120	*	NS	NS	NS	NS			C18, C24

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
RTU : LIQUID-READY TO USE
SC/L : SOLUBLE CONCENTRATE/LIQUID

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
C18 : Do not discharge effluent containing this pesticide into sewage systems without notifying the sewage treatment plant authority.
C24 : Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water. (NPDES license restriction)
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)		Max. Appl. Rate (AI unless noted otherwise)		Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Geographic Limitations Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED													
ADHESIVES, INDUSTRIAL						Use Group: INDOOR NON-FOOD							
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W	80	W	200	*	NS		NS	NS			
	WP	W	75	W	188	*	NS		NS	NS			
COATINGS, INDUSTRIAL						Use Group: INDOOR NON-FOOD							
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	WP	W	75	W	75	*	NS		NS	NS			
COMMERCIAL/INDUSTRIAL WATER COOLING SYSTEMS						Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment., Initial., Metering pump., Not Applicable., Not applicable for this use.	SC/L	V	20	V	20	*	NS		NS	NS			A30
Water treatment., Subsequent/maintenance., Metering pump., Not Applicable., Not applicable for this use.	SC/L	V	8	V	8	*	NS		NS	NS			A30
PAINTS, LATEX/OIL/VARNISH (APPLIED FILM)						Use Group: INDOOR NON-FOOD							
Industrial preservative treatment., During manufacture., Not on label., Not Applicable., Not applicable for this use.	SC/L	W	800	W	1200	*	NS		NS	NS			
	WP	W	750	W	2250	*	NS		NS	NS			
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	V	625	V	1250	*	NS		NS	NS			
PAPER/PAPER PRODUCTS						Use Group: INDOOR NON-FOOD							
Industrial preservative treatment., During manufacture., Calender., Not Applicable., Not applicable for this use.	SC/L	W	400	W	400	*	NS		NS	NS			
	WP	W	400	W	400	*	NS		NS	NS			
Industrial preservative treatment., During manufacture., Press., Not Applicable., Not applicable for this use.	SC/L	W	400	W	400	*	NS		NS	NS			
	WP	W	400	W	400	*	NS		NS	NS			

SITE Application Type, Application Timing, Application Equipment) Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)		Max. Appl. Rate (AI unless noted otherwise)		Soil Tex. Max. Dose	Max. Apps @ Max Rate	Maximum Dose /crop cycle or /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Disallowed	Use Limitations Codes
USES ELIGIBLE FOR REREGISTRATION													
NON-FOOD/NON-FEED (con't)													
PULP/PAPER MILL WATER SYSTEMS						Use Group: AQUATIC NON-FOOD INDUSTRIAL							
Water treatment., Continuous feed (initial)., Not on label., Not Applicable., Not applicable for this use.	WP	W	4	W	9	*	NS	NS	NS	NS			A30
Water treatment., Intermittent (slug)(initial)., Not on label., Not Applicable., Not applicable for this use.	WP	W	4	W	9	*	NS	NS	NS	NS			A30
TEXTILES/TEXTILE FIBERS/CORDAGE						Use Group: INDOOR NON-FOOD							
Preservative treatment., Not on label., Not on label., Not Applicable., Not applicable for this use.	SC/L	W	800	W	1200	*	NS	NS	NS	NS			
	WP	W	750	W	1125	*	NS	NS	NS	NS			

LEGEND

HEADER ABBREVIATIONS
Max. Apps @ Max Rate : Maximum number of Applications at Maximum Dosage Rate
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)

SOIL TEXTURE FOR MAX APP. RATE
* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES
SC/L : SOLUBLE CONCENTRATE/LIQUID
WP : WETTABLE POWDER

ABBREVIATIONS
AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet, briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part, parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE
DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

USE LIMITATIONS CODES
A30 : Preclean for heavily soiled areas.
* NUMBER IN PARENTHESES REPRESENTS THE NUMBER OF TIME UNITS (HOURS,DAYS, ETC.) DESCRIBED IN THE LIMITATION.

APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 2-Mercaptobenzothiazole and Salts covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 2-Mercaptobenzothiazole and Salts in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in 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 in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). 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 appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Sodium 2-Mercaptobenzothiazole

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	MO	41601401
61-2A	**Start. Mat. & Mnfg. Process**	MO	41601401
61-2B	**Formation of Impurities**	MO	41601401
62-1	**Preliminary Analysis**	MO	41601402
62-2	**Certification of limits**	MO	41601402
62-3	**Analytical Method**	MO	41601402
63-2	**Color**	MO	41601403
63-3	**Physical State**	MO	41601403
63-4	**Odor**	MO	41601403
63-5	**Melting Point**	MO	41601403
63-6	**Boiling Point**	MO	41601403
63-7	**Density**	MO	41601403
63-8	**Solubility**	MO	42580801
63-9	**Vapor Pressure**	MO	41601403, 41651201
63-10	**Dissociation Constant**	MO	41601403
63-11	**Octanol/Water Partition**	MO	41651201, 41601403
63-12	**pH**	MO	41601403
63-13	**Stability**	MO	42598001
63-14	**Oxidizing/Reducing Action**	MO	42848201

Data Supporting Guideline Requirements for the Reregistration of Sodium 2-Mercaptobenzothiazole

REQUIREMENT		USE PATTERN	CITATION(S)
63-15	**Flammability**	MO	41601403
63-16	**Explodability**	MO	41601403
63-17	**Storage stability**	MO	43206101
63-18	**Viscosity**	MO	41601403
63-20	**Corrosion characteristics**	MO	41651201, 43206102
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	MO	42267101
71-2A	**Avian Dietary - Quail**	MO	42428501
72-1C	**Fish Toxicity Rainbow Trout**	MO	42233201
72-2A	**Invertebrate Toxicity**	MO	42226001
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	MO	41567201
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	MO	Waived
81-3	**Acute Inhalation Toxicity - Rat**	MO	Waived
81-4	**Primary Eye Irritation - Rabbit**	MO	Waived
81-5	**Primary Dermal Irritation - Rabbit**	MO	Waived
81-6	**Dermal Sensitization - Guinea Pig**	MO	Waived
82-1A	**90-Day Feeding - Rodent**	MO	Waived
82-3	**90-Day Dermal - Rodent**	MO	42146301
83-3A	**Developmental Toxicity - Rat**	MO	41422201, 41422202

Data Supporting Guideline Requirements for the Reregistration of Sodium 2-Mercaptobenzothiazole

REQUIREMENT		USE PATTERN	CITATION(S)
83-4	**2-Generation Reproduction - Rat**	MO	41912501
84-2A	**Gene Mutation (Ames Test)**	MO	41045601, 41045602, 41045603, 41045604
84-4	**Other Genotoxic Effects**	MO	41525501
85-1	**General Metabolism**	MO	41123401, 41123402, 41123403
231	**Applicator Dermal Exposure**	MO	41412201
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	MO	41601401
161-1	**Hydrolysis**	MO	Required

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Zinc 2-Mercaptobenzothiazole

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	M	41602301
61-2A	**Start. Mat. & Mnfg. Process**	M	41602301, 42700701
61-2B	**Formation of Impurities**	M	41602301, 42700701
62-1	**Preliminary Analysis**	M	41602302
62-2	**Certification of limits**	M	41602302
62-3	**Analytical Method**	M	41602302, 42478701
63-2	**Color**	M	41602303
63-3	**Physical State**	M	41602303
63-4	**Odor**	M	41602303
63-5	**Melting Point**	M	41602303
63-7	**Density**	M	41602303
63-8	**Solubility**	M	41602303, 42867801
63-9	**Vapor Pressure**	M	41651401
63-10	**Dissociation Constant**	M	41602303
63-11	**Octanol/Water Partition**	M	41651401
63-12	**pH**	M	41602303
63-13	**Stability**	M	41602303, 42601301
63-14	**Oxidizing/Reducing Action**	M	42867801
63-15	**Flammability**	M	42867801

Data Supporting Guideline Requirements for the Reregistration of Zinc 2-Mercaptobenzothiazole

REQUIREMENT		USE PATTERN	CITATION(S)
63-16	**Explodability**	M	41602303
63-17	**Storage stability**	M	43283901
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	M	42267101
71-2A	**Avian Dietary - Quail**	M	42428501
72-1C	**Fish Toxicity Rainbow Trout**	M	42233201
72-2A	**Invertebrate Toxicity**	M	42226001
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	M	41571901
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	M	41571902
81-3	**Acute Inhalation Toxicity - Rat**	M	Waived
81-4	**Primary Eye Irritation - Rabbit**	M	41571903
81-5	**Primary Dermal Irritation - Rabbit**	M	41571904
81-6	**Dermal Sensitization - Guinea Pig**	M	41571905
82-3	**90-Day Dermal - Rodent**	M	42146301
83-3A	**Developmental Toxicity - Rat**	M	41422201, 41422202
83-4	**2-Generation Reproduction - Rat**	M	41912501
84-2A	**Gene Mutation (Ames Test)**	M	41045601, 41045602, 4145603, 4145604
84-4	**Other Genotoxic Effects**	M	41525501

Data Supporting Guideline Requirements for the Reregistration of Zinc 2-Mercaptobenzothiazole

REQUIREMENT		USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**	M	41602301
161-1	**Hydrolysis**	M	Waived

APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of 2-Mercaptobenzothiazole and Salts

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. 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, are 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 also attempted 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 whenever a 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 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 identifying 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 standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, 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 the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained 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 the 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. 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," which stands 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.

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MRID	CITATION
41045601	Godek, E.G.; Naismith, R.W.; Matthews, R.J. 1984. Ames Salmonella/Microsome Plate Test. Study No. PH301-CMA-001-83. Unpublished study conducted by Pharmakon Research International and submitted by CMA.
41045602	Godek, E.G.; Naismith, R.W.; Matthews, R.J. 1984. CHO/HGPRT Mammalian Cell Forward Gene Mutation Assay. Study No. PH314-CMA-001-83. Unpublished study conducted by Pharmakon Research International and submitted by CMA.
41045603	Cifone, M.A.; Myhr, B.C. 1985. Mutagenicity Evaluation of Mercaptobenzothiazole in the Mouse Lymphoma Forward Mutation Assay. Study No. 20989. Unpublished study conducted by Litton Bionetics and submitted by CMA.
41045604	Sorg, R.M.; Naismith, R.W.; Matthews, R.J. 1984. Genetic Toxicology Micronucleus Test. Study No. PH309A-CMA-001-83. Unpublished study conducted by Pharmakon Research International and submitted by CMA.
41123401	Hill, D.L. 1986. Disposition of 2-Mercaptobenzothiazole-Ring UL-14C and 2-Mercaptobenzothiazole Disulfide-Ring-UL-14C in Fischer 344 Male and Female Rats Dosed Orally. Study No. SORI-86-451. Unpublished study conducted by Southern Research Institute and submitted by CMA.
41123402	Hill, D.L. 1987. Absorption and Disposition of 2-Mercaptobenzothiazole-Ring UL-14C and 2-Mercaptobenzothiazole Disulfide-Ring-UL-14C in Fischer 344 Male and Female Rats and Female Guinea Pigs Dosed Topically. Study No. SORI-86-1200. Unpublished study conducted by Southern Research Institute and submitted by CMA.
41123403	Hill, D.L. 1986. Washing Efficacy in Removal of 2-Mercaptobenzothiazole-Ring UL-14C and 2-Mercaptobenzothiazole Disulfide-Ring-UL-14C from Fischer 344 Male and Female Rats and Female Guinea Pigs Dosed Topically. Study No. SORI-86-1137. Unpublished study conducted by Southern Research Institute and submitted by CMA.
41412201	Popendorf, W.; Selilm, M.; Kross, B. 1990. Chemical Manufactureres Association. Antimicrobial Exposure Assessment Study: Lab Project ID:

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MRID	CITATION
	Q626. Unpublished study prepared by Univ. of Iowa, Institute of Agricultural Medicine and Occupational Health. 209 p.
41422201	Rodwell, D. 1989. Range-finding Teratology Study in Rats with MBT: Final Report: Lab Project Number: 3205.1 Unpublished study prepared by Springborn Life Sciences, Inc. 125 p.
41422202	Rodwell, D.E. 1989. Teratology Study in Rats with MBT. Study No. SLS 3205.2. Unpublished study conducted by Springborn Laboratories and submitted by R.T. Vanderbilt Co.
41525501	Curren, R.D. 1990. Unscheduled DNA Synthesis in Rat Primary Hepatocytes. Study No. T9190.380. Unpublished study conducted by Microbiological Associates and submitted by R.T. Vanderbilt. Also 41544801.
41567201	Reagan, E. 1990. Acute Oral LD50 of Sodium 2-Mercaptobenzothiazole (NACAP) in Sprague-Dawley Rats: Lab Project Number 90.3530.021. Unpublished study prepared by Food and Drug Research Laboratories. 84 p.
41571901	Reagan, E. 1990. Acute Oral LD50 Study of Zinc 2-Mercaptobenzothiazole (ZETAX) in Sprague-Dawley Rats. Unpublished study prepared by Food and Drug Laboratories.
41571902	Reagan, E. 1990. Acute Dermal Toxicity Study of Zinc, 2-Mercaptobenzothiazole (ZETAX) in New Zealand White Rabbits. Unpublished study prepared by Food and Drug Research Laboratories.
41571903	Reagan, E. 1990. Primary Eye Irritation Study of Zinc 2-Mercaptobenzothiazole (ZETAX) in New Zealand White Rabbits. Unpublished study prepared by Food and Drug Research Laboratories.
41579904	Reagan, E. 1990. Primary Dermal Irritation Study of Zinc 1-Mercaptobenzothiazole (ZETAX) in New Zealand White Rabbits. Unpublished study prepared by Food and Drug Research Laboratories.
41571905	Biesemeier, J.A. 1990. Dermal Sensitization Study of Zinc, 2-Mercaptobenzothiazole (Zetax) in Guinea Pigs. Study No. 90.3530.020. Unpublished study conducted by FDRL and submitted by R.T. Vanderbilt.

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MRID	CITATION
41601401	Flynn, F. 1990. Product Identity and Composition of Sodium 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co, Inc. 44 p.
41601402	Flynn, F. 1990. Analysis and Certification of Product Ingredients of Sodium 2-Mercaptobenzothiazole (50 percent aqueous solution). Unpublished study prepared by R. T. Vanderbilt, Co., Inc. 17 p.
41601403	Flynn F.; Agahigian, H. 1990. Physical and Chemical Characteristics of Sodium 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt in association with Baron Consulting Co. 7 p.
41602301	Flynn, F. 1990. Product Identity and Composition of Zinc 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co, Inc. 17 p.
41602302	Flynn, F. 1990. Analysis and Certification of Ingredients of Zinc 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 14 p.
41602303	Flynn F.; Agahigian, H. 1990. Physical and Chemical Characteristics of Zinc 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt in cooperation with Baron Consulting Co. 6 p.
41651201	Flynn F.; Agahigian, H. 1990. Physical and Chemical Characteristics of Sodium 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt in association with Baron Consulting Co. 4 p.
41651401	Flynn F.; Agahigian, H. 1990. Physical and Chemical Characteristics of Zinc 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt in cooperation with Baron Consulting Co. 4 p.
41912501	Rodwell, D.E. 1990. Two-Generation Reproduction Study in Rats with MBT. Study No. 3205.5. Unpublished study conducted by Springborn Laboratories and submitted by R.T. Vanderbilt Co.
42146301	Siglin, J.C. 1991. A 91 Day Dermal Toxicity Study in Rats with MBT. Study No. 3248.1. Unpublished study conducted by Springborn Laboratories and submitted by R.T. Vanderbilt Co. 345 p.

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MRID	CITATION

42226001 Collins, M. 1992. 2-Mercaptobenzothiazole (ROKON) --Acute Toxicity to Daphnids (*Daphnia magna*) Under Static Conditions. Lab Project Number: 92-2-4118. Unpublished study prepared by Springborn Laboratories, Inc. 58 p.

42233201 Collins, M. (1992) "(2-Mercaptobenzothiazole) (ROKON): Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) under Static Conditions": Lab Project Number: 92-2-4125. Unpublished study prepared by Springborn Labs, Inc. 55 p.

42267101 Pederson, C.; Helsten, B. (1992) 2-Mercaptobenzo-thiazole (ROKON) -- 14 Acute Oral LD50 Study in Bobwhite Quail: Lab Project Number: BLAL 121-005-03. Unpublished study prepared by Bio-Life Associates, Ltd. 45 p.

42428501 Pederson, C.; Helsten, B. (1992) 2-Mercaptobenzo-thiazole (ROKON): 8-Day Acute Dietary LC50 in Bobwhite Quail: Lab Project Number: 121-004-01. Unpublished study prepared by Bio-Life Associates, Ltd. 68 p.

42478701 Flynn, F.; Gallagher, T. 1990. Supplement to MRID 41602302. Analysis and Certification of Product Ingredients. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 6.p.

42580801 Flynn, F.; Gallagher, T. 1992. Solubility of Sodium 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 6 p.

42598001 Wells, D. 1992. Stability of Sodium 2-Mercaptobenzo-thiazole. Supplement to MRID 41601403: Lab Project Number: 92-10-4471. Unpublished study prepared by Springborn Labs, Inc. 52 p.

42601301 Wells, D. 1992. Stability of Zinc 2-Mercaptobenzo-thiazole. Supplement to MRID 41602303. Unpublished study prepared by Springborn Labs. Inc. 57 p.

42700701 Uniroyal Chemical Co., Inc. 1993. OXAF Accelerator: Product Chemistry, Discussion of Beginning Materials, Manufacturing Process and Theoretical Formation of Impurities: A Supplement. Unpublished Study. 48 p.

42848201 Gallagher, T.; Flynn, F. 1993. Oxidizing/Reducing Action of Sodium 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 6 p.

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MRID	CITATION
42867801	Gallagher, T.; Flynn, F. 1993. Solubility of Zinc 2-Mercaptobenzothiazole and Oxidizing/Reducing Action of Zinc 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 9 p.
43206101	Gallagher, T.; Flynn, F. 1994. Storage Stability of Sodium 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co., Inc. and B. F. Goodrich Specialty Polymers and Chemicals Division. 8 p.
43206102	Gallagher, T.; Flynn, F. 1994. Corrosion Characteristics of Sodium 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 13 p.
43283901	Gallagher, T.; Flynn, F. 1994. Storage Stability Study of Zinc 2-Mercaptobenzothiazole. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 11 p.
	Dapson, S. C.; Rinde, E. 1992. U.S. EPA HED Carcinogenicity Peer Review. Memorandum 10025.
	Dieter, M.P. 1988. National Toxicology Program Technical Report on the Toxicology and Carcinogenesis of 2-Mercaptobenzothiazole (CAS No. 149-30-4) in F344/N Rats and B6C3F1 Mice (Gavage Studies). Technical Report No. 332.
	Office of Prevention and Toxic Substances. 1992. Summary of Stream Dilution Factor Program (SDFP) Outputs for 40 Industrial Categories (Updated January, 1991, 1Q10 & 3Q5 Added October, 1992).

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to the Sodium and Zinc Salts of 2-Mercaptobenzothiazole. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for Sodium and Zinc Salts of 2-Mercaptobenzothiazole and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters

2. Detailed Label Usage Information System (LUIS) Report

3. 2-Mercaptobenzothiazole and Salts RED Fact Sheet

4. PR Notice 86-5 (included in this appendix)

5. PR Notice 91-2 (included in this appendix) pertains to the Label Ingredient Statement

APPENDIX E. PR Notices 86-5 and 91-2

PR Notice 86-5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 29, 1986

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 86-5

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS
AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the

entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

- INDEX-

A. Organization of Submittal Package

A "submittal package" consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this Notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to one study, they should be included as an appendix to that study.

- If such materials relate to more than one study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an

application for an EUP should be subdivided into sections A, B, C,... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (i.e., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e g , Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study.

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product

produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

c. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed "example" cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1. Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; **DO NOT INCLUDE CBI ON THE TITLE PAGE**. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identity on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c) (See Attachment 3). These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI

claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(D)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked "Confidential Attachment." An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5. Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit

disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (See Part G below) must be provided ln three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the "Supplemental Statement of Data Confidentiality Claims".
- Remove the "Confidential Attachment".
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact John Carley, Chief, Information Services Branch, Program Management and Support Division, (703) 305-5240.

/S/

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

[+]Smith Chemical Corporation 1234 West Smith Street Cincinnati, OH 98765	-and-	Jones Chemical Company 5678 Wilson Blvd Covington, KY 56789

[+]Smith Chemical Corp will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it. Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

Vol n Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

* Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C).

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 6§10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ Signature _____

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, of courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information in voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1. (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE REFERENCE	LINES	REASON FOR THE DELETION	FIFRA
6	14	Identity of Inert Ingredient	§10(d)(C)
28	25	"	"
100	19	"	"

Example 2. (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

( )
(Reproduce the deleted paragraph(s) here)
( )

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20.	2-17	Description of the quality control process	§10(d)(1)(C)

Example 3. (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PAGES(S): are attached immediately behind this page

PAGES	REASON FOR THE DELETION	FIFRA REFERENCE
35-41.	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1._____

2._____

3._____

Submitter_____

Sponsor_____

Study Director_____

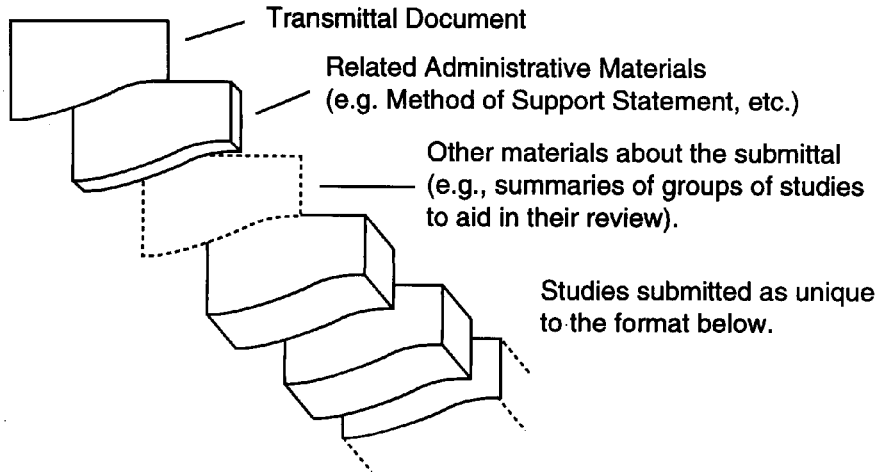
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

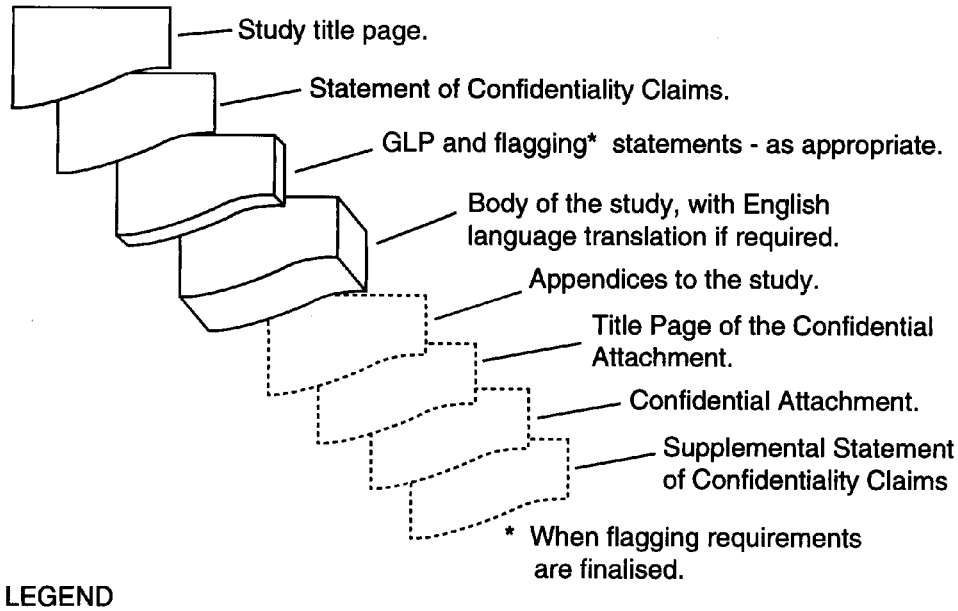
Submitter_____

ATTACHMENT 7.

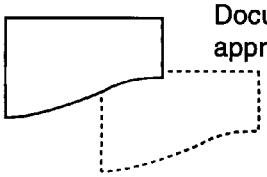
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



Documents which must be submitted as appropriate to meet established requirements.

Documents submitted at submitter's option.

PR Notice 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

PR NOTICE 91-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual

product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section l0(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE,"** all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be **set based on representative sampling** and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient StatementS must be changed to nominal concentration.

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 153.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentrations on the application form. These types Or amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 308-7031.

/s/
Anne E. Lindsay, Director
Registration Division (H-7505C)

APPENDIX F. Product Specific Data Call-In

DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice

Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines 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 (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your

election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must

also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is 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 do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated

instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

   a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

   b. fulfill the commitment to develop and submit the data as required by this Notice; or

   c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for

suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3. 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 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C <u>EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS</u>

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain 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, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Louis P. True, Jr., Acting Director
Special Review and
Reregistration Division

Attachments

1 - Data Call-In Chemical Status Sheet
2 - Product-Specific Data Call-In Response Form
3 - Requirements Status and Registrant's Response Form
4 - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration

5 - EPA Acceptance Criteria
6 - List of Registrants Receiving This Notice
7 - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

Attachment 1. Chemical Status Sheet

SODIUM AND ZINC SALTS OF 2-MERCAPTOBENZOTHIAZOLE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing sodium and zinc salts of 2-Mercaptobenzothiazole.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of sodium and zinc salts of 2-Mercaptobenzothiazole. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this sodium and zinc sodium salts of 2-Mercaptobenzothiazole Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for sodium and zinc salts of 2-Mercaptobenzothiazole are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on the sodium and zinc salts of 2-Mercaptobenzothiazole are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible the sodium and zinc salts of 2-Mercaptobenzothiazole products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic database of the sodium and zinc salts of 2-Mercaptobenzothiazole, please contact Kathleen Depukat at (703) 308-8587.

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Franklin Gee at (703) 308-8008.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Sue Rathman
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: Sodium and Zinc Salts of 2-Mercaptobenzothiazole

Attachment 2. Product Specific Data Call-In Response Forms (Form A inserts) Plus Instructions

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-4. Already completed by EPA.

Item 5. If you wish to **voluntarily cancel** your product, answer "**yes**." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)**; you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.

Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**."

Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes**." If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.

Item 9. **Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation**

Requirements" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed **"Certification of Offer to Cost Share in the Development Data" form**. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another

registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed **"Certification With Respect To Data Compensation Requirements" form (EPA Form 8570-29)** and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

NOTE: You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 3. Product Specific Requirement Status and Registrant's Response Forms (Form B inserts) and Instructions

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3. Completed by EPA. Note the unique identifier number assigned by EPA in item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guidelines reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use patters (s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/ or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. lt is normally based on 8 months after issuance of the Reregistration Eligibility Documents unless EPA determines that a longer time period is necessary.

Item 9. Enter Only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement. I understand that this option is available on for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this notice that my product is similar. Enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product my be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am

submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed " Certification of offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the require data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgrade (upgrading a study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this Option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s) number (s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registratrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be require to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within

30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status chosen. I also understand that the deadline for submission of data as specified by the original data cal-in notice will not change.

Items 10-13. Self-explanatory.

NOTE:You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Attachment 4. EPA Batching of End-Use Products for Meeting Data Requirements for Reregistration

EPA'S BATCHING OF PRODUCTS CONTAINING THE SODIUM AND ZINC SALTS OF 2-MERCAPTOBENZOTHIAZOLE FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing the active ingredients sodium and zinc salts of 2-mercaptobenzothiazole, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

The table below shows two EPA registrations which were placed into one batch.

BATCH NO.	EPA REG. NO.	% of 2-Mercaptobenzothiazole & salts & other active ingredients	Formulation Type
1	1965-26	4.0% - 2-Mercaptobenzothiazol, zinc salt 46.0% - Zinc dimethyldithiocarbamate	Wettable Powder
	34822-5	4.0% - 2-Mercaptobenzothiazol, zinc salt 46.0% - Zinc dimethyldithiocarbamate	Wettable Powder

The table below shows one EPA registration which was not batched because it contained different salts of the active ingredients and different inerts. In addition, the concentration of active and inert ingredients varied from the other registrations.

EPA REG. NO.	% of 2-Mercaptobenzothiazole & salts & other active ingredients	Formulation Type
1965-8	2.4% - 2-Mercaptobenzothiazol, sodium salt 27.6% - Sodium dimethyldithiocarbamate	Soluble Concentrate

Attachment 5. EPA Acceptance Criteria

SUBDIVISION D

Guideline	Study Title
Series 61	Product Identity and Composition
Series 62	Analysis and Certification of Product Ingredients
Series 63	Physical and Chemical Characteristics

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Name of technical material tested (include product name and trade name, if appropriate).

2.____ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient.

3.____ Name and upper certified limit for each impurity or each group of impurities present at $\geq$ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at $<$ 0.1%.

4.____ Purpose of each active ingredient and each intentionally-added inert.

5.____ Chemical name from Chemical Abstracts index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert.

6.____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient.

7.____ Description of each beginning material in the manufacturing process.
- ____ EPA Registration Number if registered;
  for other beginning materials, the following:
- ____ Name and address of manufacturer or supplier.
- ____ Brand name, trade name or commercial designation.
- ____ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity.

8.____Description of manufacturing process.
- ____ Statement of whether batch or continuous process.
- ____ Relative amounts of beginning materials and order in which they are added.
- ____ Description of equipment.
- ____ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained.
- ____ Statement of whether process involves intended chemical reactions.
- ____ Flow chart with chemical equations for each intended chemical reaction.
- ____ Duration of each step of process.
- ____ Description of purification procedures.
- ____ Description of measures taken to assure quality of final product.

9.____ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at $\geq$ 0.1% or was found at $\geq$ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3).

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1.____ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at > 0.1%.
2.____ Degree of accountability or closure > ca 98%.
3.____ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans). [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.].
4.____ Complete and detailed description of each step in analytical method used to analyze above samples.
5.____ Statement of precision and accuracy of analytical method used to analyze above samples.
6.____ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient.
7.____ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined.
8.____ Upper certified limit proposed for each impurity present at > 0.1% and for certain toxicologically significant impurities at < 0.1% along with explanation of how limit determined.
9.____ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described.
10.____ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy.

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color
____ Verbal description of coloration (or lack of it)
____ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State
____ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
____ Based on visual inspection at about 20-25E C

63-4 Odor
____ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
____ Observed at room temperature

63-5 Melting Point
____ Reported in EC
____ Any observed decomposition reported

63-6 Boiling Point
____ Reported in EC
____ Pressure under which B.P. measured reported
____ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity
____ Measured at about 20-25E C
____ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20E C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility
____ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
____ Measured at about 20-25E C
____ Reported in g/100 ml (other units like ppm acceptable if sparingly soluble)

63-9 Vapor Pressure
____ Measured at 25E C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25E C)
____ Experimental procedure described
____ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant
____ Experimental method described
____ Temperature of measurement specified (preferably about 20-25EC)

63-11 Octanol/water Partition Coefficient
____ Measured at about 20-25E C
____ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
____ Data supporting reported value provided

63-12 pH
____ Measured at about 20-25E C
____ Measured following dilution or dispersion in distilled water

63-13 Stability
____ Sensitivity to metal ions and metal determined
____ Stability at normal and elevated temperatures
____ Sensitivity to sunlight determined

SUBDIVISION F

Guideline	Study Title
81-1	Acute Oral Toxicity in the Rat
81-2	Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig
81-3	Acute Inhalation Toxicity in the Rat
81-4	Primary Eye Irritation in the Rabbit
81-5	Primary Dermal Irritation Study
81-6	Dermal Sensitization in the Guinea Pig

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ At least 5 young adult rats/sex/group.
3.____ Dosing, single oral may be administered over 24 hrs.
4. *___ Vehicle control if other than water.
5.____ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6.____ Individual observations at least once a day.
7.____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8.____ Individual daily observations.
9.____ Individual body weights.
10.____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-2 Acute Dermal toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1._____ Identify material tested (technical, end-use product, etc).
2._____ At least 5 animals/sex/group.
3.*_____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4._____ Dosing, single dermal.
5._____ Dosing duration at least 24 hours.
6.*_____ Vehicle control, only if toxicity of vehicle is unknown.
7._____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8._____ Application site clipped or shaved at least 24 hours before dosing.
9._____ Application site at least 10% of body surface area.
10._____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11._____ Individual observations at least once a day.
12._____ Observation period to last at least 14 days.
13._____ Individual body weights.
14._____ Gross necropsy on all animals.

Criteria marked with an * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 µm or less).
3.____ At least 5 young adult rats/sex/group.
4.____ Dosing, at least 4 hours by inhalation.
5.____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6.____ Chamber temperature, 22E C (+2°), relative humidity 40-60%.
7.____ Monitor rate of air flow.
8.____ Monitor actual concentrations of test material in breathing zone.
9.____ Monitor aerodynamic particle size for aerosols.
10.___ Doses tested, sufficient to determine a toxicity category or a limit dose (5 mg/L actual concentration of respirable substance).
11.___ Individual observations at least once a day.
12.___ Observation period to last at least 14 days.
13.___ Individual body weights.
14.___ Gross necropsy on all animals.

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult rabbits.
4.____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6.____ Solid or granular test material ground to a fine dust.
7.____ Eyes not washed for at least 24 hours.
8.____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.*___ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.____ Identify material tested (technical, end-use product, etc).
2.____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.____ 6 adult animals.
4.____ Dosing, single dermal.
5.____ Dosing duration 4 hours.
6.____ Application site shaved or clipped at least 24 hours prior to dosing.
7.____ Application site approximately 6 cm^2.
8.____ Application site covered with a gauze patch held in place with nonirritating tape.
9.____ Material removed, washed with water, without trauma to application site.
10.___ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.*__ Individual daily observations.

Criteria marked with an * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1.___ Identify material tested (technical, end-use product, etc).
2.___ Study not required if material is corrosive or has a pH of < 2 or > 11.5.
3.___ One of the following methods is utilized:
_____ Freund's complete adjuvant test
_____ Guinea pig maximization test
_____ Split adjuvant technique
_____ Buehler test
_____ Open epicutaneous test
_____ Mauer optimization test
_____ Footpad technique in guinea pig.
4.___ Complete description of test.
5.*__ Reference for test.
6.___ Test followed essentially as described in reference document.
7.___ Positive control included (may provide historical data conducted within the last 6 months).

Criteria marked with an * are supplemental and may not be required for every study.

Attachment 6. List of All Registrants Sent This Data Call-In (insert) Notice

Attachment 7. Cost Share Data Compensation Forms, Confidential Statement of Formula Form and Instructions

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

EPA

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved

OMB No. 2070-0106
2070-0057

Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA 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(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 3-31-96

Please fill in blanks below.

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are: (check one)

   [ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA Form 8570-31 (4-90)

APPENDIX G. FACT SHEET

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-94-024 September 1994

R.E.D. FACTS

Sodium and Zinc Salts of 2-Mercapto-benzothiazole

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2380, the sodium and zinc salts of 2-mercaptobenzothiazole.

Use Profile

This case includes two active ingredients, the sodium and zinc salts of 2-mercaptobenzothiazole, which are used as fungicides, microbiocides and bacteriostats. These salts are used as preservatives for adhesives, latex and oil paints, paper products, metal working cutting fluids and textile fibers.

Sodium 2-mercaptobenzothiazole is used in the form of a soluble concentrate or liquid to control mold, mildew, bacteria and fungi which cause aqueous industrial products to degrade. The metal working cutting fluid use of the sodium salt of 2-mercaptobenzothiazole is the only use pattern where effluent containing the chemical is discharged into aquatic environments, potentially exposing non-target aquatic organisms, including endangered species. This use pattern exceeds the acute Level of Concern (LOC) for endangered aquatic organisms. The Agency, therefore, has determined that effluent containing sodium 2-mercaptobenzothiazole should

not be discharged into streams and other waterways where endangered aquatic organisms are known to reside. When the Agency completes its Endangered Species Program, additional precautionary labeling may be required to mitigate the risk to endangered species.

Zinc 2-mercaptobenzothiazole is used in the form of a soluble concentrate or liquid and wettable powder to control mold, mildew, bacteria and fungi which degrade aqueous industrial products, fabrics, and yarns; and slime-forming bacteria and fungi in industrial water systems.

There are no registered food uses for either the sodium or zinc salts of 2-mercaptobenzothiazole.

Regulatory History

Sodium 2-mercaptobenzothiazole was first registered as a pesticide in the United States in 1949 in an industrial preservative product. Currently, only one product is registered, for use in wood and paper/paperboard treatment and as a preservative in metal working cutting fluids, emulsions, textiles and pastes.

Zinc 2-mercaptobenzothiazole was first registered as a pesticide in the United States in 1955 in an industrial preservative product. Currently, two products are registered for use as preservatives in adhesives, textiles, paints, coatings and paper products.

The parent compound, acid of 2-mercaptobenzothiazole, was registered as a pesticide active ingredient in 1956. However, all products containing that chemical have since been canceled.

Human Health Assessment

Toxicity

Zinc 2-mercaptobenzothiazole has been placed in Toxicity Category III, which indicates moderate to low acute toxicity, for acute skin and eye effects. However, the sodium salt is placed in Toxicity Category I, indicating the highest degree of acute toxicity, for skin and eye effects because it is extremely acidic (with a Ph of 11.5).

The acid of 2-mercaptobenzothiazole is classified as a non-quantifiable "Group C" carcinogen; a possible human carcinogen. A linear, multi-stage model for cancer risk assessment was not appropriate because the use of this pesticide is not likely to result in repeated human exposure over a significant portion of the human life span. Margins of Exposure (MOEs) were calculated to quantify the risk to applicators/mixers/loaders. The MOEs for the preservative and metal working cutting fluid uses of zinc and sodium 2-mercaptobenzothiazole exceed 100 (the margin considered acceptable) by several orders of magnitude. Therefore, additional exposure studies were not warranted, and the Agency required data on acute, developmental and subchronic toxicity and mutagenicity only.

Occupational and Residential Exposure

The methods of application for products containing sodium or zinc 2-mercaptobenzothiazole that include open pouring of liquid concentrate,

and open pouring of powder into adhesives and paints, present the potential for dermal and inhalation exposure to applicators. Dermal exposure is the primary route of exposure of sodium and zinc 2-mercaptobenzothiazole.

EPA was concerned about the risks of dermal and inhalation exposure associated with the application of sodium 2-mercaptobenzothiazole for the metal working cutting fluid use, and required a dermal exposure study to assess the risks to workers. The study was designed to reflect typical work practice involving the biocide in industrial use. The final assessment of the study indicated that some absorption into the skin occurred. However, since there are no special toxicological concerns about the sodium or zinc salts, EPA is not imposing Personal Protective Equipment (PPE) requirements on use of the products.

Post-application exposure from treated paint, adhesives, textiles and other treated industrial products are not considered significant because of the low concentration/dilution factor to the treated products. There are no residential uses of sodium or zinc 2-mercaptobenzothiazole. Therefore, the potential for any significant residential exposure is very low.

Human Risk Assessment

The sodium and zinc salts are not registered for any food or feed related uses, so no dietary risks are posed. The potential for residential exposure and risk is very low.

Workers (mixers, loaders and applicators) may be exposed to these pesticides, especially during open pouring of liquid and powder formulations. However, the Agency has determined that use of these pesticides is not likely to result in repeated human exposure over a significant portion of the human life span. The establishment of active ingredient based PPE requirements is not warranted at this time. The PPE for pesticide handlers will be based on the acute toxicity of the end-use product.

Environmental Assessment

Environmental Fate

A hydrolysis study has been required on the technical grade of sodium 2-mercaptobenzothiazole for industrial use products where effluent is potentially discharged into aquatic environments. While the Agency has required the study to be based on the industrial use pattern, major environmental exposure to the sodium salt is not expected. The Agency will use the results of the study to confirm this assessment and the degradation rate of the active ingredient and products formed during hydrolysis.

Ecological Effects Risk Assessment

2-Mercaptobenzothiazole is almost nontoxic to birds on an acute oral basis and is only slightly toxic to birds on a dietary basis. However, it is highly toxic to freshwater fish and moderately toxic to aquatic invertebrates. The use patterns of the sodium and zinc salts, except for sodium

2-mercaptobenzothiazole's use in metal working cutting fluids, indicate that they will not pose risks to avian and aquatic species.

Unlike agricultural situations, where aquatic organisms can be exposed to pesticides via runoff or spray drift, nontarget aquatic organisms would be exposed to industrial microbiocides through a point source discharge. The metal working cutting fluids use of the sodium salt is the only use pattern which may result in an effluent discharge into aquatic environments. It therefore poses the potential for exposure to nontarget aquatic organisms, including endangered species.

EPA's aquatic risk assessment indicates that minimal risk is posed to freshwater aquatic organisms in receiving streams at mean flow rates. However, under high exposure conditions, a high acute and chronic risk is posed to freshwater aquatic organisms. The high exposure scenario also exceeds the LOC for endangered freshwater fish and invertebrate species. Therefore, effluent containing sodium 2-mercaptobenzothiazole should not be discharged into streams and other waterways where endangered aquatic organisms are known to reside.

Additional Data Required

A hydrolysis study has been required to confirm the environmental assessment by determining the degradation rate of sodium 2-mercapto-benzothiazole and products formed during hydrolysis. EPA also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised product labeling for reregistration of products containing sodium or zinc salts of 2-mercaptobenzothiazole.

Product Labeling Changes Required

The labels of all registered pesticide products containing sodium and zinc salts of 2-mercaptobenzothiazole must comply with EPA's current pesticide labeling requirements. The following statement also must appear on the labels of sodium 2-mercaptobenzothiazole end use products with the metal working cutting fluid use:

> **Effluent Discharge Labeling Statement** - "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

When the Agency completes the Endangered Species Program, additional precautionary labeling may be required to mitigate the risk to endangered species.

Regulatory Conclusion

The use of registered products containing sodium or zinc salts of 2-mercaptobenzothiazole will not pose unreasonable risks or adverse effects to humans or the environment, provided that these products are used in accordance with the restrictions on product labeling. Therefore, all uses of these products are eligible for reregistration. Sodium or zinc salts of 2-mercaptobenzothiazole products will be reregistered once the confirmatory generic data, the required product-specific data, Confidential Statements of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for sodium and zinc salts of 2-mercaptobenzothiazole during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Following the comment period, the sodium and zinc salts of 2-mercaptobenzothiazole RED document will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the sodium and zinc salts of 2-mercaptobenzothiazole RED, or reregistration of individual products containing sodium and zinc salts of 2-mercaptobenzothiazole, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 6:00 pm Central Time, Monday through Friday.