US Environmental Protection Agency
Office of Pesticide Programs

Reregistration Eligibility Decision for Formaldehyde and Paraformaldehyde

June 2008

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-08-004
June 2008

Reregistration Eligibility Decision for Formaldehyde and Paraformaldehyde (Case 0556)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial formaldehyde and paraformaldehyde. The enclosed Reregistration Eligibility Decision (RED) document was approved on June 30, 2008.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for formaldehyde and paraformaldehyde and their associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for formaldehyde and paraformaldehyde are available to the public on EPA's Pesticide Docket at: www.regulations.gov. The docket number is EPA-HQ-OPP-2008-0121.

The formaldehyde and paraformaldehyde RED was developed through EPA's public participation process, published in the Federal Register on September 10, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the formaldehyde and paraformaldehyde risk assessment and the attached RED document concern only these particular pesticides. This RED presents the Agency's conclusions on the dietary, drinking water, occupational, residential and ecological risks posed by exposure to formaldehyde and paraformaldehyde alone. This document also identifies both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days

from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that formaldehyde and paraformaldehyde will be eligible for reregistration provided that all the conditions identified in this document are satisfied. Sections IV and V of this RED document describe the necessary labeling amendments for end-use products and data requirements. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that will accompany the DCI.

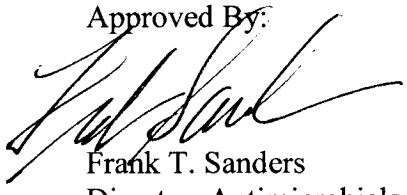
If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, ShaRon Carlisle, at (703) 308-6427. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY DECISION
for
Formaldehyde and Paraformaldehyde
Case 0556

Approved By:



Frank T. Sanders
Director, Antimicrobials Division
June 30, 2008

Attachment

Table of Contents

Formaldehyde and Paraformaldehyde Reregistration Team

Health Effects Risk Assessment
Timothy F. McMahon
Jonathan Chen
Srivivas Gowda
A. Najm Shamim
Timothy C. Dole
Timothy Leighton

Ecological Risk Assessment
Richard C. Petrie

Environmental Fate Risk Assessment
A. Najm Shamim

Registration Support
Marshall Swindell

Risk Management
ShaRon Carlisle
Diane Isbell

GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
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
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for formaldehyde and paraformaldehyde and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of formaldehyde and paraformaldehyde that pose risks of concern. As a result of this review, EPA has determined that formaldehyde and paraformaldehyde containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database 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 or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the Agency's revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for formaldehyde and paraformaldehyde. The formaldehyde and paraformaldehyde case consists of one PC code each: 043001 (formaldehyde), 043002 (paraformaldehyde). The first product containing formaldehyde was registered in 1967.

Formaldehyde as an antimicrobial pesticide is used as a fumigant in agricultural premises such as poultry and swine farms and processing plants as well as in citrus and mushroom houses. It is also used as a hard surface disinfectant in commercial premises, industrial premises and veterinary clinics. Formaldehyde containing products are also used in oil drilling wells for preservation of processing waters. Formaldehyde is also registered as a materials preservative for consumer products such as laundry detergents, general purpose cleaners and wall paper adhesives. Paraformaldehyde is used for in-drawer fumigation of hair cutting equipment and as a mildewcide in closets and unoccupied vacation homes. The currently registered formaldehyde products are formulated as liquid concentrates or liquid ready to use solutions with formaldehyde concentrations that range from 2.28% to 54%. The paraformaldehyde products are formulated as solids with paraformaldehyde concentrations of 62.3% and 91%.This suggests there are only 2 formulations. Just want to ensure this is not a range.

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary or drinking water exposures based on the registered use patterns and there are no tolerances or tolerance exemptions for the use of formaldehyde and paraformaldehyde as an active ingredient. Therefore, a FQPA hazard analysis is not necessary at this time.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of formaldehyde and paraformaldehyde. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for formaldehyde

and paraformaldehyde referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0121).

This document consists of six sections. Section I is the Introduction. Section II provides a chemical overview, a profile of the use and usage of formaldehyde and paraformaldehyde and its regulatory history. Section III, Summary of Formaldehyde and Paraformaldehyde Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management and Reregistration, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

Formaldehyde

The first product containing formaldehyde was registered in the United States on January 25, 1967, for use as a fumigant. Currently there are 6 active products under PC Code 043001. There are no inert ingredient uses for this chemical. Formaldehyde is used primarily as a fumigant in agricultural premises such as poultry and swine farms and processing plants as well as in citrus packing and mushroom houses. It is used as a hard surface disinfectant in commercial premises, industrial premises and veterinary clinics. Formaldehyde is also registered as a materials preservative for consumer products such as laundry detergents, general purpose cleaners and wall paper adhesives.

Paraformaldehyde

Paraformaldehyde is a white crystalline solid formed by polymerization of formaldehyde. In 1964, paraformaldehyde was registered as a sanitizer and fungicide for use on barber and beauty shop equipment. Currently there are 2 active products under PC Code 043002. Steri-Dri™Fumigant (Registration #397-6) is used as bacteriostat, fungicide, and sanitizer in hair/beauty salons and barber shops, and Sun Pac(Registration #4972-43) is used primarily as mildewcide in closets and unoccupied vacation homes. There are no inert ingredient uses for this chemical. EPA issued a Registration Standard for paraformaldehyde in May 31, 1988.

B. Chemical Identification

Formaldehyde Molecular Structures:

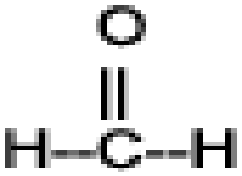


Figure 1. Formaldehyde (Gas)

Figure 2. Formaldehyde (In Water)

Common Name: Formaldehyde (Gas)
Aqueous Formaldehyde solution (in water)

Chemical Name: Formaldehyde (Gas)
Formaldehyde monohydrate (Aqueous solution)

Other Names: Formaldehyde
Formalin

OPP Chemical Codes: 043001

CAS Registry No.: 50-00-0

Case Number: 0556

Empirical Formula: CH_2O (Gas or anhydrous form)
$H_2C(OH)_2$ or $C_1H_4O_2$ (Formaldehyde monohydrate)

Molecular Weight: 30.03 (Gas)
48.03 (Aqueous solution)

Manufacturers: Champion Technologies,
Hess & Clark, Inc.,
Baker Petrolite Corporation,

Highest Percent of Active Ingredient: 54%

Formulation Types Registered:

Technical Grade (TGAI):	None.
Manufacturing Use Products (MP):	Soluble Concentrate
End Use Products (EP):	Soluble Concentrate, ready to use solution

Chemical Properties: Formaldehyde gas is colorless with a pungent, suffocating odor; it is readily soluble in water. It has a boiling point of -19.5ºC, melting point of -92ºC, a density of 0.815 g/mL at 20ºC with a vapor pressure of 3,890 mm Hg @ 25ºC. Formaldehyde is gas at room temperature and, therefore, has no pH. Formaldehyde gas is unstable and can polymerize quite easily. It is corrosive to metals and has a flashpoint of 60ºC.

Commercially formaldehyde is sold as formalin, a 37% to 55% by weight aqueous solution in water, usually with 0.5% to 15% methyl alcohol added to prevent polymerization to a solid crystalline form. In water, it exists as formaldehyde monohydrate and its chemical formula is $H_2C(OH)_2$.

A 37% Formaldehyde solution is a colorless liquid with a pungent odor. It is 100% miscible in water and has a boiling point of 101ºC. It has a density of 8.75 lbs/gal and sp gr. of 1.08 at 20ºC. It is soluble in organic solvents such as ether, alcohol, acetone and benzene. It has a vapor pressure of 1.3 mm Hg at 68ºF, and 67- 88 mm Hg at 98ºF.

Paraformaldehyde Molecular Structures:

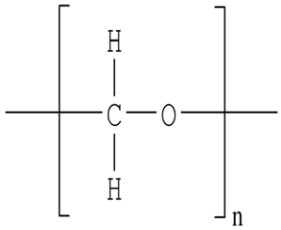


Figure 1. Paraformaldehyde

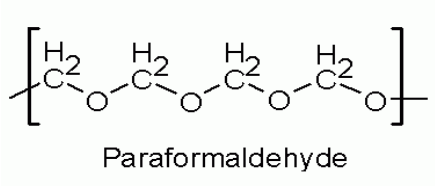


Figure 2. Paraformaldehyde

Common Name: Paraformaldehyde

Chemical Name: Paraformaldehyde

OPP Chemical Codes: 043002

CAS Registry No.: 30525-89-4

Case Number: 0556

Empirical Formula: $HO(CH_2O)_nH$ (n = 6 - 100)

Molecular Weight: (30.03)n g/mole

Manufacturers: Protexall Products Inc
Noble Pine Products Co.,

Highest Percent of Active Ingredient: 95%

Formulation Types Registered:

Technical Grade (TGAI):	None
Manufacturing Use Products (MP):	None
End Use Products (EP):	Crystalline

Chemical Properties: Paraformaldehyde is a white crystalline solid with an irritating odor. It is the polymerized form of formaldehyde. It has a melting point of 120 to 170ºC, density of 1.46 g/ml at 15ºC, bulk density of 750 to 850 kg/m3, and sp gr. of 1.4. Solubility in water is partial and is dependent on pH, temperature and molecular weight. It is insoluble in most organic solvents and very soluble in dilute alkali and acids. It has a vapor pressure of 1.45 mm Hg at 25ºC and 1 mm Hg at 30ºC. It has a pH of 3.5- 4.5 and is moderately corrosive

C. Use Profile

The following information is a description of the currently registered uses of formaldehyde and paraformaldehyde products, and an overview of use sites and application methods. A detailed table of the uses for formaldehyde and paraformaldehyde that are eligible for reregistration can be found in Appendix A.

Formaldehyde

Type of Pesticide: Disinfectant (Bacteriocide/ Germicide), Sanitizer, Microbicide/ Microbistat, Fungicide

Use Sites:

Agricultural premises and equipment
Chicken and Turkey farms
Swine operations
Dairy farms
Cattle farms
Veal farms

Emu and ostrich farms
Federally inspected meat and poultry establishments *except* where meat and food products are handled.
Poultry and swine premises and confinement areas
Hatching egg washing/fumigating treatment
Citrus packing houses
Iris and daffodil bulbs in bulb farms
Mushroom houses, equipment and premises

Commercial, institutional and industrial premises and equipment
Hard non-porous surfaces
Rooms and Railway cars

Residential and public access premises
Zoos
Veterinary clinics, kennels
Pet shops

Industrial processes and water systems
Oil recovery injection water systems
Drilling muds, work over fluids and water based packer fluids

Formulation Types: soluble concentrate and ready to use

Methods and Rates of Application:

A summary of the formaldehyde registered uses is given in Table 1 and a more detailed listing is included in Appendix A. Formaldehyde application sites include agricultural premises and equipment, railroad car fumigation and oil production. Formaldehyde is also registered as an in can preservative for use in consumer products. Formaldehyde is not registered for use in paints.

Table 1: Formaldehyde Use Site and Application Rates

In Container Preservative	8133-32	Use range = 0.1 to 1000 ppm in final product.
Poultry and Livestock Bldgs and Equipment. Vet Clinics and Kennels	134-65	Spray all surfaces to saturation using 1-3 oz product/gallon.
		Wet mist using an automatic wet fogger and 1 ¼ - 2 ½ oz product/gallon.
Poultry and swine premises and confinement areas	8133-32	Use 20-60 oz. product/1000 ft^3. *Sprinkler application*: Use a 1:11 dilution *Spray Sled*: Use a 1:4 dilution
Egg Hatcher/Incubator	8133-32	Use a maximum of 1 fl. oz./30 ft^3. Place in an open container and allow to evaporate. After the 19^{th} day of incubation, use ½ fl.

Use Site	Label #	Application Rates and Instructions
		oz/30ft^3.
Citrus packing houses	8133-32	Use 16 fl. oz product/1000 ft^3. Apply using a stationary mounted spray manifold and suitable air operated foggers. Premises may be treated up to twice a year.
Mushroom houses, equipment and premises	8133-32	*Non Producing areas*: Inject solution into steam (1 gallon per 5,500 - 6650 ft^3)
Rooms and Railway cars	8133-32	For each 1000 ft^3, use 16 $^2/_3$ oz potassium permanganate and 20 oz of product.
Oil recovery injection water systems	8133-28 10707-43	Inject 25-5000 ppm active ingredient for continuous treatment or slug application.
Drilling muds, work over fluids and water based packer fluids		Inject 100-500 ppm active ingredient for continuous treatment or slug application

Paraformaldehyde

Type of Pesticide: Disinfectant, bacteriocide, algaecide, fungicide

Use Sites:

Residential and Public Access Premises
Bathroom premises (cabinets, drawers and closets)
Kitchen premises (cabinets, drawers and closets)
Human bedding
Barber shops and beauty salons (cabinets and drawers)

Formulation Types: crystalline

Methods and Rates of Application:

A summary of the paraformaldehyde registered uses is given in Table 2 and a more detailed listing is included in Appendix A.

Table 2: Paraformaldehyde Use Site and Application Rates

Closets (Clothing and Linen)	4972-43	Hang cloth bag in closet or lay on shelf or in drawer. Contents of this bag will treat up to 700 cubic feet. For musty odor in bedding, place one bag Sun Pac along with mattress, quilts, blankets, sheets in sealed closet space no greater than 100 cubic feet. Leave articles 24 hours.
Vacation Homes	4972-43	When closing home for vacation or season, place one bag Sun Pac for each 700 cubic feet of space. Use only in unoccupied rooms. Rooms must be ventilated thoroughly before reentry.
Hair/Beauty Salons and Barber Shops	397-6	Remove cap, place Steri-dri in sanitizer cabinets, implement drawers, roller trays, student implement kits, covers or doors which are to be kept tightly closed.

III. Summary of Formaldehyde and Paraformaldehyde Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for formaldehyde and paraformaldehyde. While the risk assessments and related addenda are not included in this document, they are available from the Federal Government Public Docket at www.regulations.gov. The docket identification number is EPA-HQ-OPP-2008-0121. Hard copies of these documents may be found in the OPP public docket which is located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m.to 4:00 p.m.

The Agency's use of human studies in the formaldehyde and paraformaldehyde risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

1. Toxicity of Formaldehyde and Paraformaldehyde

A brief overview of the toxicity studies used for determining endpoints in the risk assessments are outlined below in Table 3. Further details on the toxicity of formaldehyde and paraformaldehyde can be found in the *Formaldehyde: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision (RED) Document*, dated 3/31/2008; and *Formaldehyde: Risk Assessments for the Reregistration Eligibility Decision (RED) Document*, dated 4/7/2008. These documents are available on the U.S. Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0121).

The Agency has reviewed all toxicity studies submitted to support guideline requirements for formaldehyde and paraformaldehyde and determined that the toxicological database is sufficient for reregistration. Major features of the toxicology profile are presented below.

a. Acute Toxicity

The acute toxicity database for formaldehyde is considered complete. Technical grade formaldehyde (37% a.i.) has a moderate order of acute toxicity in experimental animals via the oral and dermal routes (Toxicity Categories II and III). Inhalation toxicity studies on formaldehyde are extensive and include both acute exposures and longer term exposures. Toxicity from acute exposures is characterized by pathology of the respiratory epithelium and has been observed in rats exposed for 4 hours to a concentration of 10

ppm (Bhalla, 1991), while longer term exposures of rats (3 ppm for 6 hours/day for 5 days) also results in respiratory tract lesions (Buckley et al., 1984). Table 3 gives a summary of the acute toxicity data.

870.1100 (§81-1)	Acute Oral – Guinea Pig Purity 37.3% - Formaldehyde	00058054	LD_{50} = 260 mg/kg	II
870.1200 (§81-2)	Acute Dermal – Rat Purity 37.3% - Formaldehyde	00058054	LD_{50} = 300 mg/kg	II
870.1200 (§81-2)	Acute Dermal – Rabbit Purity 37.3% - Formaldehyde	00058054	LD_{50} = 240 mg/kg	II
870.1200 (§81-2)	Acute Dermal – Dog Purity 37.3% - Formaldehyde	00058054	LD_{50} = 550 mg/kg	II
870.1300 (§81-3)	Acute Inhalation – Mouse and Rat	See Open Literature studies in Toxicity Profile for Formaldehyde		
870.2400 (§81-4)	Primary Eye Irritation - Purity 37.3% - Formaldehyde	00058054	Severe eye irritant	I
870.2500 (§81-5)	Primary Dermal Irritation Purity 37.3% - Formaldehyde	00058054	Formation of vesicles with superficial necrosis or nodules.	I
870.2600 (§81-6)	Dermal Sensitization – Guinea pigs Purity 40.0% - Formaldehyde	40161103	Extreme Sensitizer	NA

b. Toxicological Endpoints

On June 12, 2008, members of the Antimicrobials Division's Toxicity endpoint Selection Committee (ADTC) met to discuss the non-cancer inhalation toxicity endpoint for formaldehyde that had been previously selected by the committee for use in conducting inhalation toxicity risk assessments for the formaldehyde reregistration eligibility decision (RED) document.

The original endpoint of 100 ppb was selected from the published report of Horvath et. al., [JAMA 259, no. 5: 701-707, 1988], who reported nasal and respiratory effects in 109 workers occupationally exposed to formaldehyde. The value of 100 ppb was selected as a NOAEL for use in occupational risk assessments, while for the general population; a value of 10 ppb was selected. This value was derived by application of a 10-fold uncertainty factor to the NOAEL value of 100 ppb to account for intraspecies variation in response in accordance with Agency policy.

During the public comment phase of the formaldehyde risk assessment, the Formaldehyde Council responded to the selection of the 100 ppb endpoint. They stated that the Agency should consider the results of a 2007 publication by Noisel et al. (Regulatory Toxicology and Pharmacology 48: 118-127), which reviewed some of the available scientific literature. This study, in the Council's opinion, "is based on human exposure rather than controlled human chamber studies and can be used for deriving a No-Observed-Adverse-Effect-Level (NOAEL) for the non-cancer endpoint for formaldehyde."

The ADTC noted both observational human exposure data as well as data compiled from exposure of human subjects under controlled conditions in the Noisel et. al., publication. Notwithstanding the need for intentional exposure data to be presented to the Agency's Human Studies Review Board, the ADTC noted that irritant effects of formaldehyde have been reported in other studies below the 0.75 ppm concentration recommended by Noisel et. al., as a safe level. Further, this recommendation is for worker populations only.

The irritant effects of formaldehyde, including both eye and nasal irritation as well as respiratory symptoms (irritation, changes in pulmonary function), can be considered from a toxicological perspective to be composed of both physiological and adverse responses. Based on the available data, the ADTC was not compelled to select a value higher than that already proposed. With respect to the 10-fold uncertainty factor used for risk assessment to the general population, the ADTC concluded that a reduction in this factor is not warranted at this time. Contrary to the Formaldehyde Council's statement that "the nature of the health effect does not suggest that there are particularly susceptible subpopulations which would warrant application of the 10x intraspecies UF," the 1999 ATSDR Toxicological Review of formaldehyde (ATSDR, 1999) noted two studies "...providing suggestive evidence that children may be more sensitive to the irritant effects of formaldehyde." These studies were not intentional exposure studies. It is also noted in the ATSDR review that "additional research is necessary to confirm or discard the hypothesis that children may be more susceptible than adults to the irritant effects of formaldehyde..."

The ADTC concluded that, based on the available data, it is appropriate to remain with the NOAEL value selected from the 1988 Horvath et. al., publication and with the 10-fold uncertainty factor for risk assessments to the general population. The ADTC is also aware, however, of ongoing efforts by ORD/NCEA to develop an inhalation reference concentration, or RfC for formaldehyde. OPP will continue to coordinate its

efforts with ORD and other program offices to refine the non-cancer inhalation assessment as necessary. The toxicological endpoints selected for various exposure scenarios are summarized below in Table 4.

Table 4. Toxicology Endpoint Selection for Formaldehyde

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE, UF, Special FQPA SF* for Risk Assessment	Study and Toxicological Effects
Dietary Risk Assessments			
Acute Dietary (general population including infants and children)	An acute dietary assessment is not needed for the registered antimicrobial uses of formaldehyde.		
Chronic Dietary (all populations)	A chronic dietary assessment is not needed for the registered antimicrobial uses of formaldehyde.		
Non-Dietary Risk Assessments			
Incidental Oral	An incidental oral risk assessment is not required for the registered antimicrobial uses of formaldehyde.		
Dermal (all durations)	A dermal risk assessment is not required for the registered antimicrobial uses of formaldehyde.		
Inhalation (all durations)	**NOAEL** (human) = 0.1 ppm	**Occupational UF = 1** **Residential UF = 10 (**10x intraspecies)	ACGIH 2001 publication on formaldehyde Horvath, E.P. et. al., (1986): JAMA 259(5): 701-707. Based on complaints of eye, nose, and throat irritation in particle board workers at concentrations of formaldehyde from 0.4 – 1.0 ppm. Redden, J. (2005): Section 18 Emergency Exemption for the use of Paraformaldehyde: U.S. Army Medical Research Institute of Infectious Diseases.
Cancer	Formaldehyde is currently classified as a B1 (probable human carcinogen) in EPA's IRIS assessment. IARC has classified formaldehyde as "carcinogenic to humans." The Agency has decided to present the formaldehyde cancer risks for the pesticidal uses using both the existing 1991 IRIS cancer unit risk of 1.3 E-5 per ($\mu g/m^3$) and the CIIT BBDR model until any new cancer estimates are fully peer reviewed.		

c. Carcinogenicity

The Agency is currently reevaluating the carcinogenic potential of formaldehyde. The historical and ongoing development of an inhalation unit risk value to assess the carcinogenic potential of formaldehyde is briefly summarized below. Contributors to this summary included scientists from several EPA program offices (Office of Pesticide Programs [OPP], Office of Pollution, Prevention, and Toxics [OPPT], Office of Research and Development /National Center for Environmental Assessment [ORD/NCEA], Office of Research and Development/National Health Effects Exposure Research Laboratory [ORD/NHEERL], and Office of Air and Radiation [OAR]).

- In 1991 IRIS published a weight-of-evidence characterization for carcinogenicity of formaldehyde, classifying formaldehyde as a B1 probable human carcinogen with a potency factor of 1.3 E-5 per ($\mu g/m^3$)) on the basis of squamous cell nasal tumors observed in a two-year study in rats (Kerns et al., 1983).

- In 1999 the Chemical Industry Institute of Toxicology (CIIT) developed a health risk assessment for formaldehyde based upon the animal toxicology data (CIIT, 1999). This document presented the dose-response modeling of these data in two distinct parts: 1) based upon a biologically-based dose response (BBDR) model, and 2) benchmark dose models that were based upon point of departures at various response levels of the tumor and precursor data. Both these approaches made extensive use of the available time-to-tumor and mechanistic information. The 1999 assessment was subsequently published in various articles in peer-reviewed journals (2001, 2002, 2003, and 2004).

- In 1999, the U.S. EPA's Office of Air and Radiation and Office of Research and Development, in conjunction with Health Canada, conducted an external peer review workshop for the CIIT BDDR model as well as an external written peer review and public comment period for their assessments. While the review was largely positive on the overall approach in the assessment, reviewers also pointed to the potential for significant uncertainty due to model mis-specification and uncertainties in key parameters involved in the BBDR model.

- Based on the peer review of the CIIT model, OAR determined in 2004 that the CIIT model was the most appropriate tool for risk assessment for formaldehyde. OAR has subsequently used the formaldehyde cancer potency derived using the CIIT model for a number of risk assessments involving formaldehyde emissions to the atmosphere such as the Plywood and Composite Wood Products National Emission Standard for Hazardous Air Pollutants (final rule 2004, reconsidered final rule 2006, remanded to EPA by court 2007); Control of Hazardous Air Pollutants from Mobile Sources (Final Rule 2007); and Proposed Rule for National Emission Standard for Combustion Turbines (2004). Health Canada, Australia, the World Health Organization, and the German Maximale Arbeitsplatzkonzentrationen (MAK) Commission have also used the CIIT model.

Model strengths include consideration of the mode of action data for formaldehyde and a conservative approach to account for potential direct DNA interaction and mutation induction. Model uncertainties include variability for some of the parameters of the model (e.g., cell proliferation) which can affect predictions of risk (Subramanian et. al., 2007; 2008 [in press]).

- In 2004, NCEA convened a panel of experts, including scientists from CIIT, to provide advice on these and other critical biological and statistical uncertainties. The strength of the CIIT model is its consideration of mode of action and extensive mechanistic information.

- Although current OAR assessments still use the CIIT model, these assessments now acknowledge previously unknown uncertainties with the CIIT model when characterizing the risk results.

- In 2004, the International Agency for Research on Cancer (IARC) characterized formaldehyde as a human carcinogen based on their review of the current literature (IARC, 2004), including data in humans on nasopharyngeal cancer, cancer of the nasal cavity and paranasal sinuses, and leukemia. It should be noted that some epidemiology studies did not find a reported association between formaldehyde exposure and carcinogenicity. For example, Coggon et. al., 2003 studied over 14,000 workers exposed to formaldehyde in industrial workplaces and reported no excesses of either leukemia or nasal and nasopharyngeal cancer.

- In 2005, the Scientific Review Panel (SRP) of the California Office of Environmental Health Hazard Assessment responded to the CA Air Resources Board request to reevaluate the carcinogenic potential of formaldehyde. The Panel noted in this 2005 review that California's Office of Environmental Health (OEHHA)'s November 2002 evaluation of a petition had included the 1999 report on the CIIT model and other information, and that OEHHA had concluded that "*the evidence…(1) did not change the determination that formaldehyde is a carcinogen; (2) presented information that considered the possibility of non-linear dose response relationships, but presented no clear grounds to review the original "no threshold" determination; and (3) did not provide any new epidemiology or bioassays supporting a change in potency. In addition, there was insufficient information to fully evaluate the CIIT model; issues such as model uncertainty were not adequately addressed….*" The Scientific Review Panel's overall conclusion in 2005 was, *"The Panel concluded that there was not sufficient new data to support the petition to review the [OEHHA's earlier 1992] formaldehyde risk assessment. In addition, the newly published studies represented relevant new information, but they did not allow determination of a causal relationship between formaldehyde exposure and leukemia. These studies deserve further evaluation over time given their potential importance."* (Froines, 2005).

- EPA is currently completing a new IRIS assessment and unit risk value for formaldehyde; the reassessment is scheduled to start internal peer review in May 2008 and begin independent external peer review in January 2009 (http://cfpub.epa.gov/ncea/iristrac/index.cfm?fuseaction=viewChemical.showChemical&sw_id=1031). EPA anticipates that the peer review of the formaldehyde assessment will be a longer process then that of EPA's reregistration process scheduled to conclude in September 2008.

Based on the on going development of the science to predict carcinogenic potential of formaldehyde, OPP has decided to present the formaldehyde cancer risks for the pesticidal uses using both the existing 1991 IRIS cancer unit risk of 1.3 E-5 per ($\mu g/m^3$) and the CIIT BBDR model until any new cancer estimates are fully peer reviewed. OPP also acknowledges the wide range in cancer risks using these approaches and will coordinate with other offices in EPA on the outcome of the upcoming peer review process on the carcinogenicity of formaldehyde. Because formaldehyde air concentrations approach those associated with ocular and respiratory tract irritation, the risk mitigation measures to be implemented in the meantime for the pesticidal uses will be based on mitigating the non-cancer effects at a limit of 0.01 ppm. It is believed that this level will reduce exposures sufficiently such that the cancer risks would not be of concern. The EPA process of regulating pesticides allows for reevaluation at any time if new information from the peer review process of the carcinogenic potential of formaldehyde warrants.

2. FQPA Safety Factor

There are no tolerances for formaldehyde or paraformaldehyde and the use patterns considered for the reregistration eligibility decision do not involve dietary exposure. As a result, an FQPA safety finding is not applicable.

3. Dietary and Drinking Water Risk

Formaldehyde is used to treat mushroom houses, equipment and premises and citrus facilities as a disinfectant treatment when food is not present. The Agency believes that the dietary exposure from citrus packing and mushroom houses will be negligible. In addition, formaldehyde is used as a materials preservative in dishwashing detergent. Formaldehyde is a gas at room temperature and it is dissolved in water. However, formaldehyde is not stable in water and has a tendency to escape from solution. Half lives in air and water are short, so it is unlikely formaldehyde persists on pots, pans, and dishes. In addition, it is not expected to contaminate ground water. Therefore, there are no dietary or drinking water concerns from the antimicrobial uses of formaldehyde.

4. Residential Exposure and Risk

The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as an MOE (Margin of Exposure) which is the ratio of estimated exposure to an appropriate NOAEL

(No Observed Adverse Effect Level). Estimated MOEs are then compared to the Target MOE, which represents the dose selected for risk assessment and uncertainty factors (UF) applied to that dose. The standard UF is 100x, which includes 10x for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10x for intraspecies variation (to account for differences within the same species).

There is one product containing formaldehyde that is labeled for use as in can preservative of consumer products such as laundry detergents, general purpose cleaners and wall paper adhesives. Use of these products can result in residential handler exposure. In addition, there is one paraformaldehyde mildewcide product that is labeled for treatment of closets and vacation homes. Use of this product could result in residential postapplication exposure to paraformaldehyde. The exposure scenarios for residential exposure are provided in Table 5. Additional information on the residential exposures to formaldehyde and paraformaldehyde can be found in the *Formaldehyde: Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (RED) Document*, dated 4/15/2008; and *Formaldehyde: Risk Assessments for the Reregistration Eligibility Decision (RED) Document*, dated 4/7/2008. These documents are available on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0121). No updated risk assessments to reference?

Table 5. Exposure Scenarios for Formaldehyde and Paraformaldehyde

Residential Handler Inhalation Exposures from Formaldehyde Uses		
Material Preservation of Laundry Detergent	Handler Exposure While Using Treated Laundry Detergent	1000 ppm product
Material Preservation of Floor and Furniture Polish and Detergent Products	Handler Exposure While Using Treated General Purpose Cleaners	150 ppm product
Material Preservation of Wall Paper Adhesive	Handler Exposure While Using Treated Wallpaper Adhesive	100 ppm product
Residential Postapplication Inhalation Exposures from Paraformaldehyde Uses		
Mildewcide for clothing and linen in closets	Post Application Exposure	4 ounce of product per 750 ft^3
Mildewcide for Vacation Homes	Post Application Exposure	4 ounce of product per 750 ft^3
Material Preservation of Wall Paper Adhesive	Post Application Exposure from Wallpaper Adhesive	100 ppm product

a. Formaldehyde Residential Handler Risk

Residential handler inhalation exposures were assessed for handlers of formaldehyde treated laundry detergent, general purpose cleaners and wall paper

adhesives. The EPA's Consumer Exposure Module (CEM) was used to estimate air concentrations resulting from the use of laundry detergent and general purpose cleaner preserved with formaldehyde. The EPA's Wall Paint Exposure Model (WPEM) was used to estimate handler inhalation as well as post application exposures resulting from the use of wall paper adhesive preserved with formaldehyde.

A summary of the residential risks for formaldehyde is included in Table 6. The non-cancer risks are of concern for three of the scenarios because the MOEs are less than the target MOE of 10. The non-cancer risk estimates are based upon EPA exposure models which are generally believed to be conservative. The fact that the vapor pressure of 1.0 mm Hg, which is based on formaldehyde as formalin, was used in these models rather than the vapor pressure of pure formaldehyde, which exists only as gas, is a source of uncertainty. There are also uncertainties regarding the use of the WPEM model because it is based on test data for paint solvents that have different physical/chemical properties than formaldehyde.

The estimated cancer risks range from $<3 \times 10^{-9}$ when using the CIIT model to 8×10^{-6} when using the IRIS unit risk. The IRIS cancer risk estimates provide an upper-bound on risk. Based on the on going reevaluationf the potential cancer and non-cancer risks of formaldehyde through the ORD Integrated Risk Information System (IRIS) program, a reevaluation may need to be done at a later date. The EPA process of regulating pesticides allows for reevaluation at any time if new information from the peer review process of the carcinogenic potential of formaldehyde warrants.

Table 6 – Residential Risk Summary for Biocidal Uses of Formaldehyde

Laundry Detergent Handler	240 ppb	**0.4**	0.5 ppb	**8×10^{-6}**	$<3 \times 10^{-9}$
General Purpose Cleaner Handler	21 ppb	**4.8**	0.12 ppb	**2×10^{-6}**	$<3 \times 10^{-9}$
Wall Paper Adhesive Handler	15 ppb	**6.7**	0.044 ppb	7×10^{-7}	$<3 \times 10^{-9}$
Wall Paper Adhesive Post Application	4.9 ppb	20	0.038 ppb	6×10^{-7}	$<3 \times 10^{-9}$

b. Formaldehyde Residential Post Application Risk

The EPA's Wall Paint Exposure Model (WPEM) was used to estimate post application exposures resulting from the use of wall paper adhesive preserved with formaldehyde. The MOE for peak exposure is 20 and is not of concern. The estimated cancer risk ranges from $<3 \times 10^{-9}$ when using the CIIT model to 6×10^{-7} when using the IRIS unit risk.

c. Paraformaldehyde Handler Residential Risk

Based on current use patterns, there are no residential handler exposures anticipated from the use of paraformaldehyde.

d. Paraformaldehyde Post Application Residential Risk

The EPA's Consumer Exposure Module (CEM) was used to estimate post application inhalation exposures resulting from the use of paraformaldehyde mildewcide in closets of occupied homes. The MOE for the mildewcide use is less than 0.1, which is below the target MOE of a10 and is of concern. The estimated cancer risk ranges from $<8 \times 10^{-7}$ when using the CIIT model to 3×10^{-3} when using the IRIS unit risk.

Conversations with the registrant of this product have indicated that it is primarily intended to be used in unoccupied homes. Although these products are used in unoccupied homes, the risks for the closet scenario are of concern because of potential difficulty providing thourough ventilation before reentry. For this reason, use in closets and other confined spaces present risk concerns.

5. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation). Acute and chronic dietary aggregate assessments were not conducted for formaldehyde because there are no uses for formaldehyde attributable to the dietary route of exposure.

6. Occupational Exposure and Risk

a. Occupational Handler Exposure and Risk

Workers can be exposed to formaldehyde through mixing, loading, applying a pesticide or re-entering treated sites. Formaldehyde is used as a fumigant for agricultural premises, in preservation, in production, and in wall paper adhesive. The Agency has very little information concerning exposure from biocidal uses for formaldehyde. Because formaldehyde has a high vapor pressure (1.0 mm Hg in formalin), the inhalation unit surrogate exposure data that are often used to estimate risks associated with pesticide use are generally not applicable. Although there are many studies of formaldehyde occupational exposures reported in the literature, these studies involved the non-biocidal uses. Therefore, it was not possible to quantitatively assess the formaldehyde exposures

that result from biocide uses; a qualitative assessment was completed based upon work practices listed on the labels.

In general, it was determined for the biocide application scenarios that if the label requirements such as closed system loading, remote application and adequate ventilation are followed, exposures would be reduced to levels that are not of concern. There are several occupational handler exposure scenarios that involve formaldehyde products. These scenarios are listed below:

- Mechanical Fumigation
- Evaporative Fumigation
- Catalyzed Evaporative Fumigation
- Hard Surface Disinfection of Animal Housing Areas and Equipment
- Material Preservation
- Oil Production
- Wall Paper Adhesive Application

The wall paper adhesive application was assessed using the WPEM model. The MOE for non-cancer risk is 1.6 which is above the target MOE of 1 and is thus not of concern. The estimated cancer risk ranges from $<1 \times 10^{-8}$ when using the CIIT model to 6×10^{-5} when using the IRIS unit risk. For additional information, please see the *Formaldehyde: Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (RED) Document*, dated 4/15/2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0121).

b. Occupational Post Application Exposure and Risk

Formaldehyde is used for fumigating poultry and swine containment buildings and post application exposure can occur when the workers re-enter the fumigated areas. These exposures were assessed using the single chamber decay formula from the Multi-Chamber Concentration and Exposure Model (MCCEM) and a ventilation rate of 4 air changes per hour. This assessment was based upon the application parameters listed in the Champion Technologies Formaldehyde Solution 37 Label (EPA Reg #8133-32). The ventilation rate is based upon poultry and animal housing design criteria; given these conditions, the formaldehyde air concentration declines to a level that is not of concern after 3 hours. For additional information, please see the *Formaldehyde: Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (RED) Document*, dated 4/15/2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0121).

7. Human Incident Data

There are many reported incidents associated with formaldehyde exposure, but only a limited few are associated with its use as an antimicrobial agent (biocide). Formaldehyde is a dermal irritant and a dermal sensitizer. The primary dermal effects

that have been reported are rash, burning sensation, itching, dry scaling irritation, cracking and thickened skin, itching, and blisters and rash on hands. Symptoms associated with eyes are the primary reported illness in all associated incidents. Nausea, dizziness, headache, and sore throat are the primary systemic effects that have been reported. Allergic reactions and asthma-like symptoms also have been reported following occupational exposures. Only limited acute cases with oral exposure to formaldehyde have been published in scientific literature. For additional information on the reported incidents, refer to the *Incidents Report Associated with Formaldehyde*, dated 1/30/2008; located on the Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2008-0121).

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated ecological hazards and environmental risks for formaldehyde and paraformaldehyde. Based on the registered antimicrobial use patterns, formaldehyde and paraformaldehyde have low potential for terrestrial or aquatic environmental exposure. Therefore, a quanitatiave risk assessment was not conducted.

For detailed discussions of all aspects of the environmental risk assessment, see the *Environmental Fate Assessment of Formaldehyde for the Issuance of the Reregistration Eligibility Decision Document*, dated January 23, 2008, and *the Ecological Hazard and Environmental Risk Assessment of Formaldehyde and Paraformaldehyde for the Reregistration Eligibility Decision (RED) Document,* dated January 29, 2008.

1. Environmental Fate and Transport

The Agency has no environmental fate and transport data for formaldehyde or paraformaldehyde and relied on open literature for fate and transport studies. Available literature indicates that there are multiple degradation pathways for formaldehyde. Paraformaldehyde off-gasses as formaldehyde from a formaldehyde/paraformaldehyde solution; therefore, the Agency has assumed that paraformaldehyde will have fate and transport behavior similar to formaldehyde.

a. Water

The half-life of formaldehyde has been reported between 24-168 hours (1-7 days) in surface water and 48-336 hours (2- 14 days) in groundwater, based on estimated aqueous aerobic biodegradation half lives. Formaldehyde, therefore, is not likely to persist in natural waters. The Agency for Toxic Substances and Disease Registry (ATSDR) notes that when formaldehyde is released into water it biodegrades to low levels in a few days.

b. Soil

A Koc value of 1.567 was estimated for formaldehyde based on open literature (ATDSR, 1999[1]) therefore, it is not expected to adsorb to soils and is likely to be mobile in soils. Compounds with a Koc value of less than <100 are considered to be moderately mobile in soils and may contaminate groundwater. Octanol/Water partition is low (log Kow = 0.65). Therefore formaldehyde is not likely bioaccumulate in aquatic organisms.

[1] ATSDR (Agency for Toxic Substances and Disease Registry). Toxicological Profile for Formaldehyde. U.S. Department of Health and Human Services. 1999.

c. Air

The half life of formaldehyde in air has been found to depend on intensity of natural light, temperature, and location. Based on its reaction with hydroxy radical using hydroxyl radical rate constant, the half life of formaldehyde in air varies between 7 to 70 hours. One study even estimated the air half life to vary between 0.3 to 250 hours. This study, however, assumed there was hydroxyl or hydroperoxyl radicals present. It is not likely to persistent in air. Degradation products from this interaction likely are: water, formic acid, carbon monoxide and an intermediate adduct likely hydroperoxyl/formaldehyde. Air photolytic half life of formaldehyde has been estimated between 1.6 to 6 hours.

2. Ecological Hazard

Formaldehyde and paraformaldehyde labeled uses including oil field uses such as treatments of drilling muds and waterfloods are considered by the Agency to pose little adverse risk to non-target organisms or listed species. Antimicrobial pesticides used in oil fields are typically minor use chemicals, diluted and greatly reduced before discharge into water, and are often regulated by other Federal or EPA offices (OW, Office of Solid Waste, OPPTS, state NPDES permits). In the case of oil fields, the US Department of the Interior, Minerals Management Service (MMS) had jurisdiction over the environmental impacts of synthetic drilling fluids in terrestrial and aquatic areas.

Terrestrial oil fields typically use berms and catch basins to prevent surface runoff of oil drilling muds and wastes from oil drilling areas. Estuarine and marine aquatic organisms may be temporarily exposed during marine drilling; however, impacts are limited to a defined area around the oil well (Neff, 2000). If the pesticide is to be used in estuarine or marine environments, three additional acute estuarine/marine toxicity studies are required. The ecological hazard assessment has determined that formaldehyde product labels must state: “This product is toxic to oysters.”

3. Risk to Listed Species

Section 7 of the Endangered Species Act (ESA), 16 U.S.C. Section 1536(a)(2), requires that federal agencies consult with the National Marine Fisheries Service (NMFS) for marine and andronomus listed species, or with the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species is to "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. §402.02.

To comply with subsection (a)(2) of the ESA, EPA's Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly appreciably reduce the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). If any of the Listed Species LOC Criteria are exceeded for either direct or indirect effects in the Agency's screening-level risk assessment, the Agency identifies any listed or candidate species that may occur spatially and temporally in the footprint of the proposed use. Further biological assessment is undertaken to refine the risk. The extent to which any species may be at risk determines the need to develop a more comprehensive consultation package as required by the ESA.

For certain use categories, including all current formaldehyde and paraformaldehyde uses, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, p 81). Uses in these categories do not undergo a full screening-level risk assessment and are considered to generally fall under a "no effect" determination, however, an endangered species effect determination will not be made at this time.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient 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 formaldehyde and paraformaldehyde as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of virtually all supported products containing formaldehyde and paraformaldehyde.

The Agency has completed its assessment of the residential, occupational and ecological risks associated with the use of pesticide products containing the active ingredient formaldehyde and paraformaldehyde. The Agency has determined that virtually all formaldehyde and paraformaldehyde containing products are eligible for reregistration provided that: 1) all risk mitigation measures are implemented; 2) current data gaps and confirmatory data needs are addressed; and 3) label amendments are made as described in Section V. Use in confined spaces such as closets is not eligible for registration because of the difficulty associated with ventilation of these spaces. Appendix A summarizes the uses of formaldehyde and paraformaldehyde that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of formaldehyde and paraformaldehyde and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of formaldehyde and paraformaldehyde, the Agency has determined that formaldehyde and paraformaldehyde products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the risk mitigation measures, submit confirmatory data as well as make the label changes identified in this document, the Agency may take regulatory action to address the risk concerns from the use of formaldehyde and paraformaldehyde. If all changes outlined in this document are fully complied with, then no risks of concern exist for the registered uses of formaldehyde and paraformaldehyde and the purposes of this determination. Once an endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decision for formaldehyde and paraformaldehyde. EPA released its preliminary risk assessment for formaldehyde and paraformaldehyde for public comment on April 23, 2008. The Agency received a comment from the registrant, as well as the Formaldeyde Council, during the 60-day

public comment period, which closed on March 23, 2008. The comments included suggestions to refine the endpoint selection.

C. Regulatory Rationale

The Agency has determined that formaldehyde and paraformaldehyde are eligible for reregistration provided that risk mitigation measures are implemented as outlined in this document, additional required data confirm this decision and label changes are made accordingly. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Residential Risk Mitigation for Formaldehyde

In order to address the risks of concern identified for the laundry detergent, general purpose cleaner and wall paper adhesive uses, maximum allowable application rates need to be reduced. The non-cancer risks (i.e., MOEs) would require product rate reductions to 40 ppm, 72 ppm and 67 ppm for the laundry detergent, general purpose cleaner and wall paper adhesive handler scenarios, respectively to achieve the target MOE of 10. However, the registrant has requested voluntary cancellation of the laundry detergent use. The non-cancer risk for the wall paper post application scenario does not require a product rate reduction. In terms of potential cancer risks, the Agency believes that the mitigation required for the non-cancer risks will adequately address these risks as well regardless of which of the current cancer approaches are used.

b. Occupational Risk Mitigation for Formaldehyde

In order to reduce potential occupational handler exposures the following mitigation is required:

- For industrial uses of formaldehyde closed systems with dry couplers (or equivilant) are required
- Structures that may be fumigated are limited to animal premises such as poultry houses and swine houses, mushroom houses, citrus packing houses, egg facilities and rail cars (not in-transit).
- All fumugiated uses must be done in such a way that the operator is outside the structure undergoing fumigation when applying the fog.
- The labels must be updated to eliminate cloth or mop applications of formaldehyde.
- Manual spray applications of formaldehyde solutions require the use of a full face respirator.
- After fumigating poultry/swine containment buildings, re-entry by unprotected persons should be allowed only after a total 12 air changes. (e.g., 3 hours of ventilation at a rate of 4 air changes per hour (ACH))

e. Occupational and Residential Risk Mitigation for Paraformaldehyde

To mitigate the occupational risks from paraformaldehyde use in beauty salons and barber shops, it is necessary that these areas have general ventilation that meets the American Society of Heating, Refrigerating and Air-conditioning Engineers (ASHRAE) recommendations and/or local exhaust ventilation that meets ACGIH recommendations.

To mitigate the residential risks from paraformaldehyde use in vacation homes, use must be limited to unoccupied structure that can be thoroughly ventilated six (6) hours prior to re-occupancy.

2. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing formaldehyde and paraformaldehyde. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that formaldehyde and paraformaldehyde are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 8). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For formaldehyde and paraformaldehyde technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call-in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. Submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact ShaRon Carlisle at (703) 308-6427 with questions regarding generic reregistration.

By US mail:

Document Processing Desk
ShaRon Carlisle
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:

Document Processing Desk
ShaRon Carlisle
Office of Pesticide Programs
(7510P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the active ingredient formaldehyde and paraformaldehyde, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. Completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (EPA Form 8570-4);

2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. Five copies of the draft label incorporating all label amendments outlined in Table 26 of this document;

4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. The product-specific data responding to the PDCI.

Please contact Marshall Swindell at (703) 308-6341 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:

Document Processing Desk
Marshall Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:

Document Processing Desk
Marshall Swindell
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of formaldehyde and paraformaldehyde has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements and are included in the generic data-call-in (DCI) for this RED. Table 8 provides an outline of the requested confirmatory data for formaldehyde and paraformaldehyde.

Table 8. Confirmatory and Conditional Data for Formaldeyde and Paraformaldehyde

90-Day Dermal Toxicity	870.3250
Developmental Toxicity in Non-Rodents	870.3700
Acute *Daphnia magna* using TGAI formaldehyde	850.1010

2. Labeling for Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 9, Label Changes Summary Table.

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 Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in will be issued at a later date.

2. Labeling for Technical and End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 9 Label Changes Summary Table.

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

document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in 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.

a. Label Changes Summary Table

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measure outlined in Section IV of the formaldehyde and paraformaldehyde RED. The following table describes how language on the labels should be amended.

Table 9 Labeling Changes Summary Table

Environmental Hazards Statements Required by the RED and Agency Label Policies	"This pesticide is toxic to oysters. 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 Pollution 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."	Precautionary Statements
End Use Products Intended for Poultry/ Swine Containment Buildings	"A minimum re-entry time of 3 hours into the fumigated area is required"	Directions for Use
End Use Products Intended for Occupational Disinfectant use	ALL Labels must be updated to eliminate mop and cloth or sponge applications	Directions for Use
End Use Products Intended for Laundry Detergent	This use has been voluntarily cancelled	
End Use Products Intended for General Purpose Cleaner	Product application rate MUST be reduced to 72 ppm	
End Use Products Intended for Wall Paper Adhesive	Product application rate MUST be reduced to 67 ppm	

FORMALDEHYDE		
Description	**Amended Labeling Language**	**Placement on Label**
End Use Products Intended for Occupational use	In order to reduce potential occupational handler exposures the following mitigation is required: • For industrial uses of formaldehyde close systems with dry couplers (or equivilant) are required • Structures that may be fumigated are limited to animal premises such as poultry houses and swine houses, mushroom houses, citrus packing houses, egg facilities and rail cars (not in-transit). • All fumugiated uses must be done in such a way that the operator is outside the structure undergoing fumigation when applying the fog. • The labels must be updated to eliminate cloth or mop applications of formaldehyde. • Manual spray applications of formaldehyde solutions require the use of a full face respirator. • After fumigation poultry/swine containment building, re-entry by unprotected persons should be allowed only after a total 12 air changes. (e.g. 3 hours of ventilation at a rate of 4 air changes per hour (ACH))	Directions for Use
_____		
End-Use Products for Vacation Homes	ALL labels must limit the use to an UNOCCUPIED structure that can be thoroughly ventilated six (6) hours prior to re-occupancy.	Directions for Use

FORMALDEHYDE		
Description	**Amended Labeling Language**	**Placement on Label**
End-Use Products for Beauty Salons and Barber Shops	This product must be used in areas with general ventilation that meets ASHRAE recommendations and/or local exhaust ventilation that meets ACGIH recommendations.	Directions for Use

VI. APPENDICES

Appendix A: Use Patterns Eligible for Reregistration for Formaldehyde (Case 0556)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Poultry and Turkey farms, Swine operations, Dairy farms, Cattle farms, Veal farms, Emu and ostrich farms	Soluble concentrate: Reg: 134-65 Reg: 8133-33	Spray or soak or fog	1 - 3 oz of product per gallon of water. ONLY FOUND directions using 3 oz for canine and feline (not those listed to the left under use site) Preclean all surfaces. Spray all surfaces to saturation. 10 minute contact time.	Ventilate closed spaces. Do not house livestock until treatment has absorbed or dried and all surfaces have been scrubbed with soap or detergent and rinsed with potable water. Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
			1 ¼ - 2 ½ oz of product per gallon of water. Wet mist until the area is moist using an approved automatic wet fogger.	
Federally inspected meat and poultry establishments *except* where meat and food products are handled.	Soluble concentrate: Reg: 134-65 Reg: 8133-33	Spray or soak or fog	1 - 3 oz of product per gallon of water. ONLY FOUND directions using 3 oz for canine and feline (not those listed to the left under use site) Preclean all surfaces. Spray all surfaces to saturation. 10 minute contact time.	Ventilate closed spaces. Do not house livestock until treatment has absorbed or dried and all surfaces have been scrubbed with soap or detergent and rinsed with potable water. Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			1 ¼ - 2 ½ oz of product per gallon of water. Wet mist until the area is moist using an approved automatic wet fogger.	
Poultry and swine premises and confinement areas	Soluble concentrate: Reg: 8133-32 Reg: 8133-33	Mechanical sprayer or sprinkler	Remove all animals. Preclean and sanitize the premises. Use 20-60 oz. of product for each 1000 ft^3 of building volume. *Sprinkler application*: Use a 1:11 dilution in an approved sprinkler system. Follow approved application methods. *Spray Sled*: Use a 1:4 dilution in an approved portable spray sled. Follow approved application methods.	For effectiveness, relative humidity should be at least 70% and ambient temperature at least 70F or higher. Reentry restrictions: Treated buildings must be left closed, locked and secured against unauthorized entry for a minimum of 24 hours. Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
Hatching egg washing/fumigating treatment	Ready to Use: Reg: 8133-32 Reg: 8133-33	Fog, fumigation	Maximum of 2 fl. oz. per 1,000 eggs in a 24-hour period. Product is to be place in an open container and allowed to evaporate or in a slight vacuum. Do not use potassium permanganate as a catalyst. Repeated at a	Incubators must be vented directly ("directly" has been removed from the label) to outside air. Fumigation may be performed on both empty incubators and incubators containing eggs. Eggs to be fumigated should be held on clean racks or egg flats which permit air circulation. Egg fumigation should NOT be done between 24 hours and

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			maximum rate of 2 fl. oz. of Formaldehyde Solution 37 per 1,000 eggs in a 24-hour period.	five days incubation because embryo damage may occur. Last treatment should be added at least 12 hours before chicks are pulled. Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
Citrus packing houses	Soluble concentrate: Reg: 8133-32 Reg: 8133-33	Fog, fumigation	Use 16 fl. Oz. of product per 1000 ft^3 of space to be treated. Product may be diluted at a rate of up to one part solution to 10 parts water. Room to be treated should be tightly closed and humidity introduced for at least 24 hours. Do not wet down with hose. Apply using an approved stationary mounted spray manifold and suitable air operated foggers. Premises may be treated up to twice a year.	Worker buffer zone: Establish a worker buffer zone of 25 feet and a residential buffer zone surrounding the treated building during treatment and aeration. See buffer zone tables from distributor. Buffer zones should be maintained for 24 hours. Reentry restrictions: Treated buildings must be left closed, locked and secured against unauthorized entry for a minimum of 24 hours. Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm. Formaldehyde is phytotoxic to citrus. Remove all fruit from spaces to be treated. Allow formaldehyde residue to dissipate from storage boxes before filling with fruit.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Iris and daffodil bulbs in bulb farms	Soluble concentrate: Reg: 8133-33	None listed on label	None listed on label	None
Mushroom houses, equipment and premises	Ready to Use: Reg: 8133-32 Reg: 8133-33	Fog, fumigation	*Non Producing areas*: Empty mushroom house of all growing media. Broom clean. Wet out growing boards. Close and seal up area to be treated. Inject steam into house until interior temperature reads 140-150F. Inject solution into steam (4 gallons for houses up to 26,600 ft^3, 5 gallons in houses up to 33,300 ft^3 and 8 gallons for houses up to 44,400 ft^3) and continue steaming for 12 hours. Turn on exhaust fan for 12 hours, then ventilate for 24 hours.	Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm. Reentry restrictions: Treated buildings must be left closed, locked and secured against unauthorized entry for a minimum of 24 hours. Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
Commercial, institutional and industrial premises and equipment				

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hard non-porous surfaces	Soluble concentrate: Reg: 134-65 Reg: 8133-33	Spray or soak or fog	1 - 3 oz of product per gallon of water. Preclean all surfaces. Spray all surfaces to saturation. 10 minute contact time.	Ventilate closed spaces. Do not house livestock until treatment has absorbed or dried and all surfaces have been scrubbed with soap or detergent and rinsed with potable water. Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
			1 ¼ - 2 ½ oz of product per gallon of water. Wet mist until the area is moist using an approved automatic wet fogger.	
Rooms and Railway cars	Ready to Use: Reg: 8133-32 Reg: 8133-33	Fog, fumigation	For each 1000 cubic feet of space, use 16 $^{2}/_{3}$ oz potassium permanganate and 20 oz of product. Place large dishpan on floor in which a smaller pan is set. Put K-permanganate in the smaller pan and pour product over it. Leave room immediately. Close all windows and doors. Ventilate after 5 hours.	Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
Residential and public access premises				

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Zoos	Soluble concentrate: Reg: 134-65	Spray, soak, mop or sponge	1 oz of product per gallon of water. Preclean all surfaces. Spray all surfaces to saturation. 10 minute contact time. Use at 3 oz per gallon to disinfect against canine parvovirus and feline panleukopenia.	Ventilate closed spaces. Do not house livestock until treatment has absorbed or dried and all surfaces have been scrubbed with soap or detergent and rinsed with potable water. Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
Veterinary clinics, kennels	Soluble concentrate: Reg: 134-65	Spray, soak, mop or sponge	1 oz of product per gallon of water. Preclean all surfaces. Spray all surfaces to saturation. 10 minute contact time. Use at 3 oz per gallon to disinfect against canine parvovirus and feline panleukopenia.	Ventilate closed spaces. Do not house livestock until treatment has absorbed or dried and all surfaces have been scrubbed with soap or detergent and rinsed with potable water. Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
Pet shops	Soluble	Spray, soak,	1 oz of product per gallon	Ventilate closed spaces. Do not house

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	concentrate: Reg: 134-65	mop or sponge	of water. Preclean all surfaces. Spray all surfaces to saturation. 10 minute contact time. Use at 3 oz per gallon to disinfect against canine parvovirus and feline panleukopenia	livestock until treatment has absorbed or dried and all surfaces have been scrubbed with soap or detergent and rinsed with potable water. Reentry restrictions: Entry into treated areas by other than correctly equipped handler is prohibited until the air concentration level of formaldehyde is LESS than 0.75 ppm.
Industrial processes and water systems				
Oil recovery injection water systems	Ready to Use: Reg: 8133-28 Reg: 8133-30 Reg: 10707-43	Injection	Inject in either a continuous treatment or slug application to produce between 25-5000 ppm of active ingredient.	For use with closed delivery systems only
Drilling muds, work over fluids and water based packer fluids	Ready to Use: Reg: 8133-28 Reg: 8133-30 Reg: 10707-43	Injection	Inject in either a continuous treatment or slug application to produce between 100-500 ppm of active ingredient.	For use with closed delivery systems only
Materials preservative				
Polishes for floors and furniture, surfactants and silicone emulsions	Ready to use: 8133-32	Incorporation	Use range = 0.10 to 1000 ppm in final product	Solution may not be used in products coming in direct contact with food and / or drinking water

Appendix A: Use Patterns Eligible for Reregistration
Paraformaldahyde case number: (0556)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Residential and public access premises				
Sanitizer Hair/beauty salons, and barber shops, sanitizer, cabinets, implement drawers, roller trays, student implement kits, covers or doors of which are to be kept tightly closed.	Ready to use Reg 397-6	Fumigant	Remove cap place in sanitizer cabinets When fungicidal action is required keep closed for 24 hours. For use in hair. beauty salons and barber shops	None mentioned

`APPENDIX B: Formaldahyde / Paraformaldahyde (case 0556)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Formaldahyde / Paraformaldahyde. These requirements apply to Formaldahyde / Paraformaldahyde in all products, including data requirements for which a technical grade active ingredient is the test substance.

830.1550	61-1	Product identity and composition		43987201, 43983801
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		42724601, 43987201, 43983801
830.1670	61-2b	Formation of Impurities		42724601, 43987201, 43983801
830.1700	62-1	Preliminary Analysis		42724601, 43987201, 43983802, 43983801
830.1750	62-2	Certification of Limits		42724601, 43987201
830.1800	62-3	Analytical Method		42724601, 43987201, 43983801
830.6302	63-2	Color		42724601, 43987201, 43983801, 57014, 57022, 57024, 7642
830.6303	63-3	Physical State		42724601, 43987201, 43983801, 57014, 57022, 76242
830.6304	63-4	Odor		42724601, 43987201, 43983801, 57014, 57022, 7642
830.7200	63-5	Melting point		43987201, 43983801, 57014, 57024, 76242
830.7300	63-7	Density or Specific Gravity		43987201, 43983801, 124869, 57014, 57024, 76242
830.7840 830.7860	63-8	Solubility		42724601, 57014, 57024, 76242

DATA REQUIREMENT				
830.7950	63-9	Vapor pressure		42724601, 43987201, 43983801, 124869, 57014, 57024, 76242
830.7370	63-10	Dissociation Constant		42930901, 43987201, 43983801
830.7550	63-11	Oct/Water partition Coef		42930901, 43987201, 43983801
830.7000	63-12	pH		42930901, 43987201, 43983801
830.6313	63-13	Stability		42930901, 43987201, 43983801, 57014, 57024, 124869
830.6315	63-15	Flammability		43987201, 43983801, 57022, 124869
830.6316	63-16	Explodability		43987201, 43983801
830.6315	63-17	Storage Stability		43987201, 43983801
830.7100	63-18	Viscosity		43987201, 43983801
830.7100	63-19	Miscibilty		43987201, 43983801
830.6320	63-20	Corrosion Characteristic		43987201, 43983801
830.6321	63-21	Dielectric Breakdown Voltage		43987201, 43983801
830.6314	63-14	Oxidation/Reduction: Chemical Incompatibility		43987201, 43983801, 57022, 124869
870.1100	81-1	Acute Oral - Rat		00058054, 00065508
870.1200	81-2	Acute Dermal - Rabbit		00058054, 00065508, 00159395
870.1300	81-3	Acute Inhalation - Rat		Open Literature, 43170601
870.2500	81-5	Primary Dermal Irritation - Rabbit		00058054, 00065514, 00159392
870.2600	81-6	Dermal Sensitization		40161103, Open Literature
870.3100	82-1a	90-Day Feeding-Rodent		00124677, 00134114, Open Literature
870-3150	82-1	90 Day oral toxicity in norodents		Open Literature

DATA REQUIREMENT				
870.3250	82-3	90-Day Dermal Toxicity-Rodent		Data Gap
870-3465	82-4	90 Day inhalation toxicity		00082134. Open Literature
870.3465	82-4	6 week inhalation toxcity		00149755
870.3700	83-3a	Developmental Toxicity -Rat		00082136, 00123770, 00123769, 00164652, Open Literature
870.3700	83-3b	Developmental Toxicity –Non rodent		Data Gap
870.3800	83-4	Reproduction and fertility effects		00143291, Open Literature
870.4100	83-1a	Chronic Toxicity-Rat		Open Literature
870.4200	83-2a	Carcinogenicity-Rat		00143288, Open Literature
870.4200	83-2b	Carcinogenicity-Mouse		Open Literature
870.4300	83-5	Combined chronic toxicity/ Carcinogenicity		00143289
870.5100	84-2	Bacterial Reverse Mutation Assay		00132156, 00138157, Open Literature
870-5200	84-2	Mouse visible specific locus test		Open Literature
870-5275		Sex- linked recessive lethal test in Dorosophlia melanogaster		Open Literature
870.5375	84-2	In Vitro mammalian chromosome aberration test		00132168, Open Literature
870.5380	84-2	Mammalian spermatogonial chromosome aberration test		Open Literature
870-5450	84-2	Rodent dominant lethal assay		Open Literature
870.5550	84-2	Unscheduled DNA synthesis in mammalian cell culture		00132169
870.5900	84-2	In Vitro sister chromatid exchange assay		Open Literature
870.5915	84-2	In Vitro sister chromatid exchange assay		Open Literature
870.6200	82-7	Neurotoxicity screening battery		Open literature

DATA REQUIREMENT				
870.6500	85-5	Schedule-controlled operant behavior		Open Literature
870.7485	85-1	General metabolism		Open Literature

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the (date) preliminary risk assessment and the related documents. EPA then considered comments on these risk assessments (which are posted to the e-docket) and revised the risk assessments. The revised risk assessments will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at www.regulations.gov

These documents include:

- Formaldehyde Preliminary Risk Assessment; Notice of Availability, (date).
- Formaldehyde Summary, (date).
- Overview of the Formaldehyde Preliminary Risk Assessment, (date).

Preliminary Risk Assessment and Supporting Science Documents:

- Formaldehyde: Preliminary Risk Assessment for the Reregistration Eligibility Decision, PC Code 043001, Case 0556, Antimicrobials Division, 4/7/08, Timothy F. McMahon, Ph.D., Jonathan Chen, Ph.D., Srivivas Gowda, Ph.D., A. Najm Shamim, Ph.D., Richard C. Petrie, Agronomist, Timothy C. Dole, CIH, Industrial Hygienist.
- Product Chemistry Science Chapter on Formaldehyde. PC Code 043001, Case 0556, Antimicrobials Division, 1/24/08, Srivivas Gowda, Ph.D.
- Product Chemistry Science Chapter on Paraformaldehyde. PC Code 043002, Case 0556,
  Antimicrobials Division, 1/24/08, Srivivas Gowda, Ph.D.
- Formaldehyde: Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision Document, PC Code 043001, Case 0556, Antimicrobials Division, 3/31/08, Timothy F. McMahon, Ph.D.
- Formaldehyde Dietary Exposure Assessments for the Reregistration Eligibility Decision. PC Code 043001, Case 0556, Antimicrobials Division, 1/29/08, A. Najm Shamim, Ph.D.
- Formaldehyde Occupational/Residential Exposure Assessment. PC Code 043001, Case 0556, Antimicrobials Division, 4/15/08, Timothy C. Dole, CIH, Industrial Hygienist.
- Health Effects of Formaldehyde in Humans. PC Code 043001, Case 0556, Antimicrobials Division, 1/30/08.

- Environmental Fate Assessment of Formaldehyde for the Reregistration Eligibility Decision (RED). PC Code 043001, Case 0556, Antimicrobials Division, 1/23/08, A. Najm Shamim, Ph.D.

- Ecological Hazard and Environmental Risk Assessment: Formaldehyde. PC Code 043001, Case 0556, Antimicrobials Division, Richard C. Petrie, Agronomist.
- Drinking Water Assessment for Formaldehyde Reregistration Eligibility Decision (RED). PC Code 043001, Case 0556, Antimicrobials Division, 1/30/08 A. Najm Shamim, Ph.D.
- Formaldehyde/Paraformadehyde - Report of the Antimicrobials Division Toxicity Endpoint Selection Committee (ADTC). PC Code 043001; 043002, Case 0556, Antimicrobials Division, Timothy F. McMahon, Ph.D.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

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 Chlorine Dioxide 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 (1999), 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.

1. MRID Studies

MRID #	Citation
00065640	Birdsong, C. L. and J.W. Avalt, Jr. (1971). Toxicity of Certain Chemicals to Juvenile Pompano. Progressive Fish Culturist.33:76-80.
00101857	Bentley, R.E. (1975). Acute Toxicity of Ten Baroid Compounds to Bluegill (Lepomis macrochirus) and Rainbow Trout (Salmo gairdneri). Unpublished study. Conducted by Bionomics, EG&G for Baroid, Division, N.L. Industries, Houston, TX.
00126394	Heitmuller, T. (1975). Acute Toxicity of Surflo-B17 to Larvae of the Eastern Oyster …, Pink Shrimp …, and Fiddler Crabs (Uca pugilator). Unpublished study. Conducted by Bionomics, EG&G for Baroid Division, N. L. Industries, Houston, TX.
00126395	Heitmuller, T. (1975). Acute Toxicity of Aldacide to Larvae of the Eastern Oyster .., Pink Shrimp …, and Fiddler Crabs (Uca pugilator). Unpublished study. Conducted by Bionomics, EG&G for Baroid Division, N. L. Industries, Houston, TX.
00126396	Heitmuller, T. (1975). Acute Toxicity of Surflo-B19 to Larvae of the Eastern Oyster …, Pink Shrimp …, and Fiddler Crabs (Uca pugilator). Unpublished study. Conducted by Bionomics, EG&G for Baroid Division, N. L. Industries, Houston, TX.
00128086	Heitmuller, T. (1975). Acute Toxicity of Surflo-B16 to Larvae of the Eastern Oyster …, Pink shrimp …, and Fiddler Crabs (Uca pugilator). Unpublished study. Conducted by Bionomics, EG&G for Baroid Division, N. L. Industries, Houston TX.
00132485	Bills, T.D., Marking, L.L., and J.H. Chandler. (1977). Formalin: Its Toxicity to Nontarget Aquatic Organisms, Persistence, and Counteraction. U.S. Fish & Wildlife Service, Invest. Fish Control 73:1-7.
00134123	McCann, J. and F. Pitcher. (1973). Russell's Incubator Fumigant: Bluegill: Test No. 577. Unpublished study. Prepared by Pesticides Regulation Division, Animal Biology Laboratory, U.S. Environmental Protection Agency, Beltsville, MD.
00134124	McCann, J., and F. Pitcher. (1973). Russell's Incubator Fumigant: Rainbow Trout: Test No. 560. Unpublished study. Prepared by Pesticides Regulation Division, Animal Biology Laboratory, U.S. Environmental Protection Agency, Beltsville, MD.
00134126	McCann, J. and F. Pitcher. (1973). Parson's Formaldehyde: Bluegill: Test No. 594. Unpublished study. Prepared by Pesticides Regulation Division, Animal Biology Laboratory, U.S. Environmental Protection Agency, Beltsville MD.
00148770	Lemon, K.A. (1985). Acute Toxicological Evaluations of Estuarine Organisms to Support Registration Action 44797-RL. Conducted by EnviroSystems, Inc. for N.L. Treating Chemical Company, Houston, TX. .
00148772	Smith, E.H. (1985). Acute Toxicity of Formalin on Daphnia magna to Support Registration Action 44797-RL. Unpublished study. Conducted by ANATEC Laboratories, Inc. for N.L. Testing Chemicals, Houston TX.

00148773 Fletcher, D.W. (1983). Report to NL Treating Chemicals/NL Industries, Inc., Eight-day Dietary LC_{50} Study with Surflo-B315 in Bobwhite Quail: BLAL No.83 QC 39. Unpublished study. Conducted by Bio-Life Associates Ltd. For NL Treating Chemicals/NL Industries, Inc.

00148774 Fletcher, D.W. (1983). Report to NL Treating Chemicals, NL Industries, Inc., Acute Toxicity Study with Surflo-B315 in Bobwhite Quail: BLAL No.83 QD 38. Unpublished study Conducted by Bio-Life Associates Ltd. For NL Treating Chemicals/NL Industries, Inc.

00148775 Fletcher, D.W. (1984). Report to NL Treating Chemicals, NL Industries, Inc., Eight-day Dietary LC_{50} Study with Surflo-B315 in Mallard Ducklings: BLAL No.83 DC 40. Unpublished study. Conducted by Bio-Life Associates Ltd. For NL Treating Chemicals/NL Industries, Inc.

00058054 Celanese Chemical Company (1976?) Toxicological Data and Health Hazards: Formaldehyde. (Unpublished study received Nov 4, 1977 under 11558-8; CDL: 232282-K)

00065508 3T1522: Laboratory Nos. 5E-6921, 5E-6923, 5E-6924, 5E- 6922. (Unpublished study received Jan 11, 1977 under 10000-4; submitted by Hallemite Lehn & Fink, Montvale, N.J.; CDL: 229296-A)

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

00082134 Coon, R.A. et al. (1970) Animal Inhalation Studies on Ammonia, Ethylene Glycol, Formaldehyde, Dimethylamine, and Ethanol. Toxicology and Applied Pharmacology 16: 646-655.

00082136 Schnurer, L.B. (1963) Maternal and foetal responses to chronic stress in pregnancy: A study in albino rats. Acta Endocrinologica, Supplement 80 ?:3-96. (Also in unpublished submission received Oct 15, 1973 under 4G1438; submitted by Chevron Chemical Co., Richmond, Calif.; CDL:095383-A)

00123769 Ranstrom, S. and Schrurer, L. (1956) Stress and Pregnancy. Acta Pathol. Microbiol. Scandinavia. Supplement III, 113-114.

00123770 Schnurer, L. (1963) Maternal and foetal responses to chronic stress in pregnancy. Acta Endocrinologica (80):3-96. (Also In unpublished submission received 1963 under 4G1438; submitted by Chevron Chemical Co., Richmond, CA; CDL:093832-T)

00124677 Driedger, A.; Walker, J.; Galloway, F. (1973) Letter sent to C. Smart dated Oct 1, 1973: "Rat tolerance to Dietary Formaldehyde: Reference No. AD-114-73, JRW-341-73." (Unpublished study; submitted by Celanese Chemical Co., Dallas, TX; CDL:094622-H)

00132156 Jagannath, D. (1978) Mutagenicity Evaluation of Dantoin DMDMH-55 40-697 737543 in the Ames Salmonella/Microsome Plate Test: LBI Project No. 20838. Final rept. (Unpublished study received May 9, 1983 under 38906-5; prepared by Litton Bionetics, Inc., sub- mitted by Glyco, Inc., Greenwich, CT; CDL:250313-A)

00132157 Haworth, S.; Lawlor, T.; Burke, P.; et al. (1982). Salmonella/Mammalian-microsome Preincubation Mutagenicity Assay (Ames Test): Test Article 447:34-3: Study No. T1804.502. (Unpublished study received May 9, 1983 under 38906-5; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:250313-B).

00132168 Thilagar, A.; Kumaroo, P.; Pant, K. (1982) Cytogenicity Study: Chinese Hamster Ovary (CHO) Cells in vitro: Test Article 447:34-1: Study No. T1802.338. (Unpublished study received May 9, 1983 under 38906-5; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:250313-M)

00132169 Thilagar, A.; Pant, K. (1982) Unscheduled DNA Synthesis in Rat Hepatocytes: Test Article 447:34-1: Study No. T1802.380002. (Un-published study received May 9, 1983 under 38906-5; prepared by Microbiological Assoc., submitted by Glyco, Inc., Greenwich, CT; CDL:250313-N)

00134114 Viguera, C.; Kundzins, M. (1960) "28-Day Oral Administration--Rats: U.F. Concentrate-85|." (Unpublished study; prepared by Hazleton Laboratories, Inc.; CDL: 105284-C)

00143288 Watanabe, F., et al. (1954) Study on the Carcinogenicity of Aldehyde. 1st Report. Experimentally Produced Rat Sarcomas by Repeated Injections of Aqueous Solution of Formaldehyde. Two unpublished translations of Japanese article published in Gann 45(2-3):451-452.

00143289 Kerns, W.D. et al. (1983) Carcinogenicity of Formaldehyde in Rats and Mice after Long-Term Inhalation Exposure. Cancer Research 43: 4382-4392.

00143291 Hurni, H. and H. Odher (1972) Reproduction Study with Formaldehyde and Hexamethylenetetr-amine in Beagle Dogs. Fd. Cosmet. Toxicol. 11: 459-462.

00149755 Rusch, G.; Rinehart, W. (1980) A 26 Week Inhalation Toxicity Study of Formaldehyde in Monkey, Rat, and Hamster: Project No. 79- 7259. Unpublished study prepared by Bio/dynamics Inc. 184 p.

00159392 Liggett, M.; Wilson, J. (1980) Irritant Effects of Acticide BG on Rabbit Skin: 79648D/THR 2. Unpublished study prepared by Huntingdon Research Centre. 5 p.

00159393 Liggett, M.; Wilson, J. (1980) Irritant Effects of Acticide BG on Rabbit Eye Mucosa: 8088D/THR3. Unpublished study prepared by Huntingdon Research Centre. 5 p.

00159395 Kynoch, S.; Charnley, B.; Ginty, J. (1980) Acute Percutaneous Toxicity to Rats of Acticide BG: 79625D/THR4. Unpublished study prepared by Huntingdon Research Centre. 5 p.

00164652 Marks, Thomas A. et al. (1980) Influence of Formaldehyde and Sonacide (Potentiated Acid Glutaraldehyde) on Embryo and Fetal Development in Mice. Teratology 22: 51-58.

40161103 Spiers, J. (1987) Formaldehyde: Skin Sensitisation Study to the Guinea Pig: (Positive Control): Laboratory Project ID: CTL/P/ 1211A. Unpublished study prepared by ICI Central Toxicology Laboratory. 28 p.

43167201 Burleigh- Flayer, H. D. and W.J. Kintigh (1992) Glutaraldehyde and Formaldehyde: Vapor Pulmonary Hypersensitivity Study in Guinea Pigs. Bushy Run Research Center (Export, PA), Union Carbide. Study ID 92U1123, dated February 28, 1992, Unpublished.

43170601 Werley et al. (1994). Glutardehyde and Formaldehyde: Sensory Irritation Study in Swiss-Webster Mice. Union Carbide Lab Project No. 91U0123.

00146665 Celanese Chemical Co., Inc. (1985) [Product Chemistry: Formaldehyde 45%]. Unpublished compilation. 19 p.

41926001 Sibinovic, K. (1991) Reichold Formaldehyde/ Methanol: Product Chemistry: Accelerated Storage Stability: Lab Project Number: C80- PC-RI-1991. Unpublished study prepared by Shaldra, Inc. 38 p.

42596708 Stupp, S. (1992) Product Chemistries and 30-Day Storage Stability of Methaform 55A: (Product renamed Formaldehyde Solution 54): Lab Project Number: CHAMP-01A-92. Unpublished study prepared by A & S Environmental Testing, Inc. 65 p.

42656801 Petrolite Corp. (1993) Formaldehyde: Physical and Chemical Characteristics. Unpublished study. 4 p.

42724601 Stupp, S. (1992) Product Chemistries and 30-Day Storage Stability of Methaform 55A: (Product renamed Formaldehyde Solution 54): Lab Project Number: CHAMP-01A-92. Unpublished study prepared by A & S Environmental Testing, Inc. 65 p.

42859001 Stupp, S. (1991) Product Chemistry and 30-Day Storage Stability of Bactron K-55W Microbiocide: Lab Project Number: C80-BACT55-PC-1990: C80-ASST-PC-1991. Unpublished study prepared by A & S Environmental Testing, Inc. 75 p.

42995401 Stupp, S. (1993) Product Chemistries and 30 Day Storage Stability of Formaldehyde Solution 54: Lab Project Number: CHAMP-01A-92. Unpublished study prepared by A&S Environmental Testing, Inc. 172 p.

42930901 Stupp, S. (1992) Product Chemistries and 30 Day Storage Stability of Formaldehyde Solution 54: Lab Project Number: CHAMP-01A-92. Unpublished study prepared by A & S Environmental Testing, Inc. 65 p.

43051601 Douglas, C. (1993) Formaldehyde-Product Identity Analysis and Certification of Product Ingredients. Unpublished study prepared by Borden Packaging and Industrial Products. 51 p.

43745001 Sibinovic, K.; Tenhaeff, S. (1995) Product Chemistry--Formaldehyde Solution 37: Lab Project Number: BORDEN-FS97-95. Unpublished study prepared by Shaldra, Inc. and Borden Chemical & Plastics. 35 p.

44952301 Sibinovic, K. (1999) Product Chemistry--Formaldehyde Solution 37F: Lab Project Number: CTI-99-PC-01. Unpublished study prepared by Shaldra, Inc. 31 p.

2.Open Literature

Citation

Neff, J.M., S. McKelvie and R.C. Ayers, Jr. (2000). "Environmental Impacts of Synthetic Based Drilling Fluids. Report prepared for MMS by Robert Ayers & Associates, Inc. August 2000. U.S. Department of the Interior, Minerals management Service, Gulf of Mexico OCS Region, New Orleans, L.A. OCS Study MMS 2000-064. 118pp.

Chenier, R. (2003). An Ecological Risk Assessment of Formaldehyde. Human and Ecological Risk Assessment. Vol. 9, No. 26 pgs.

Canadian Environmental Protection Act (1999). Priority Substances List Assessment Report. Formaldehyde. Health Canada. 102 pgs.

ATSDR (Agency for Toxic Substances and Disease Registry). Toxicological Profile for Formaldehyde. U.S. Department of Health and Human Services. 1999.

Concise International Chemical Assessment Document 40 (CICADS) on Formaldehyde Published Under IPCS (The International Programme on Chemical Safety, Geneva, 2002. 116 pgs.

ACGIH (American Conference of Governmental Industrial Hygienists). (2001). Acrolein in Documentation of the Threshold Limit Values and Biological Exposure Indices, 7th Ed. Cincinnati, OH: American Conference of Governmental Industrial Hygienists.

Alexandersson, R. and Hedenstierna, G. (1988). Respiratory Hazards Associated with Exposure to Formaldehyde and Solvents in Acid-Curing Paints. Arch. Env. Health. 43: 222-227.

Alexandersson, Rolf, M.D. and Hedenstierna, Goran, M.D. (1989). Pulmonary Function in Wood Workers Exposed to Formaldehyde: A Prospective Study. Arch. Env. Health. Vol. 44, No. 1. p. 5-11.

ATSDR (Agency for Toxic Substances and Disease Registry). (1999). Toxicological Profile for Formaldehyde. U.S. Department of Health and Human Services, Public Health Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA. July 1999.

BEST (The Board on Environmental Studies and Toxicology). (2007). Formaldehyde. Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants Vol. 1. Page 103-138. The National Academies Press.

Blair, A., R. Saracci, P.A. Stewart, R.B. Hayes, and C. Shy. (1990). Epidemiologic evidence on the relationship between formaldehyde exposure and cancer. Scand. J. Work Environ. Health 16(6):381-393.

Burkhart KK, Kulig KW, McMartin KE. (1990). Formate levels following a formalin ingestion. Vet Hum Toxicol 32:135-137.

Collins, J.J., J.F. Acquavella, and N.A. Esmen. (1997). An updated meta-analysis of formaldehyde exposure and upper respiratory tract cancers. J. Occup. Environ. Med. 39(7):639-651.

Dally, K. A., Eckamnn, A. D., Hanrahan, L. P, Anderson, H.A., and Kanarek, M. S. (1981). A follow-up study of indoor air quality in Wisconsin homes. International Symposium on Indoor Air Pollution, Health and Energy Conservation, October 13-16,

Dally, K. A., Hanrahan, L. P, Woodbury, M. A., and Kavarek, M. S. Formaldehyde exposure in non-occupational environments. Arch. Environ. Health 36: 277-284 (1981).

Edling, C.; Odkvist, L.; Hellquist, H. (1985): Formaldehyde and the Nasal Mucosa. Br. J. Ind. Med. 42: 570-571.

Eells JT, McMartin KE, Black K, et al. (1981). Formaldehyde poisoning: Rapid metabolism to formic acid. JAMA, J Am Med Assoc 246:1237-1238.

Engel, H.O. and Calnan, C.D. (1966). Resin dermatitis in a Car Factory. Brit. J. Ind. Med. 23: 62-66.

Feinman SE, editor. (1988). Formaldehyde sensitivity and toxicity. Boca Raton (FL): CRC Press Inc;.

Fleischer, J.M. (1987). Medical student's exposure to formaldehyde in gross anatomy laboratories, NY State J. Med., 87: 385–388.

Flyvholm, M.A.; Hall, B.M.; Agner, T.; Tiedemann, E.; Greenhill, P.; Vanderveken, W.; Freeberg, F.E.; and Menne, T. (1997). Threshold for occluded formaldehyde patch test in formaldehyde-sensitive patients: Relationship to repeated open application test with a product containing formaldehyde releaser. Contact Dermatitis 36:26-33.

Hanrahan, L. P, Anderson, H. A., Dally, K. A., Eckamnn, A. D., and Kanarek, M. S. (1981). An investigation of the off gassing decay function in aging mobile homes with climate corrected formaldehyde readings. International Symposium on Indoor Air Pollution, Health and Energy Conservation, October 13-16 1981.

Hanrahan, LP; Dally, KA.; Anderson, HA.; Kanarek, MS. And Rankin, J.(1984). Formaldehyde vapor in mobile homes: a cross sectional survey of concentrations and irritant effects. Am J Public Health. 74: 1026–1027.

Hauptmann, M., J.H. Lubin, P.A. Stewart, R.B. Hayes, and A. Blair. (2003). Mortal- ity from lymphohematopoietic malignancies among workers in formaldehyde industries. J. Natl. Cancer Inst. 95(21):1615-1623.

Hauptmann, M., J.H. Lubin, P.A. Stewart, R.B. Hayes, and A. Blair. (2004). Mortality from solid cancers among workers in formaldehyde industries. Am. J. Epidemiol. 159(12):1117-1130.

Holmstrom et al. (1989) Histological Changes in the Nasal Mucosa in Persons Occupationally Exposed to Formaldehyde Alone and in Combination with Wood Dust. Acta Otolaryngol (Stockh) 107:120-129.

Horvath EP, Anderson H, Pierce WE, Hanrahan L, Wendlick J. (1985). The effects of formaldehyde on the mucus membranes and lungs in an industrial population. Submitted to US Department of Labor for proposed rulemaking for exposure to formaldehyde (50 FR 50412, December 10, 1985).

Horvath Jr., E.P., H. Anderson Jr., W.E. Pierce, L. Hanrahan, and J.D. Wendlick. (1988). Effects of formaldehyde on the mucous membranes and lungs: A study of an industrial population. JAMA 259(5):701-707.

Horvath, E. P. Jr.et al. (1988). Effects of Formaldehyde on the Mucous Membranes and Lungs: A Study of an Industrial Population. JAMA, Vol. 259, No.5. p. 701-707.

IARC (International Agency for Research on Cancer). (1995). Formaldehyde. Pp. 217-362 in Wood Dust and Formaldehyde. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 62. Lyon, France: World Health Organization, International Agency for Research on Cancer.

IARC (International Agency for Research on Cancer). (2004). Formaldehyde (Group 1). IARC Monographs Programme on the Evaluation of Carcinogenic Risks to Humans, Vol. 88. International Agency for Research on Cancer, World Health Organization, Lyon

Japanese Contact Dermatitis Research Group (1982). [Standard patch test allergens for 1981 in Japan.] Skin Res. (Hifu), 24: 514-525 (in Japanese).

Kochhar R, Nanda V, Nagi B, et al. (1986). Formaldehyde-induced corrosive gastric cicatrization: Case report. Hum Toxicol 5:381-382.

Kriebel D, Sama SR, Cocanour B. (1993). Reversible pulmonary responses to formaldehyde: A study of clinical anatomy students. Am Rev Respir Dis 148:1509-1515.

Kulle JT, Sauder LR, Hebel JR, Green D, Chatham MD. (1987). Formaldehyde dose-response in healthy nonsmokers. J Air Pollution Control Assoc 37:919-924.

Liteplo, R.G., and M.E. Meek. (2003). Inhaled formaldehyde: Exposure estimation, hazard characterization, and exposure-response analysis. J. Toxicol. Env. Health. Part B. 6:85-114.

Main, DM and Hogan, TJ. (1983). Health effects of low-level exposure to formaldehyde, J. Occup. Med. 25:896–900

Malaka T, Kodama AM. (1990). Respiratory health of plywood workers occupationally exposed to formaldehyde. Arch Environ Health 45:288-294

Marzulli F.N., Maibach H.J. (1973). Antimicrobials: experimental contact sensitization in man. J Soc Cosmet Chem 24:399-421.

NAC (National Advisory Committee). (2003). Acute Exposure Guideline Levels (AEGLs) for Formaldehyde. Draft1:02/2003. National Advisory Committee/AEGL, U.S. Environmental Protection Agency, Washington, DC.

NAC (National Advisory Committee). (2003). Acute Exposure Guideline Levels (AEGLs) for Formaldehyde. Draft1:02/2003. National Advisory Committee/AEGL, U.S. Environmental Protection Agency, Washington, DC.

OEHHA (Office of Environmental Health Hazard Assessment). (1999). Determination of Acute Reference Exposure Levels for Airborne Toxicants: Acute Toxicity Summary - Formaldehyde. CalEPA

Partanen, T. (1993). Formaldehyde exposure and respiratory cancer - A meta analysis of the epidemiologic evidence. Scand. J. Work Environ. Health 19(1):8-15.

Paustenbach, D., Y. Alarie, T. Kulle, N. Schachter, R. Smith, J. Swenberg, H. Witschi, and S.B. Horowitz. (1997). A recommended occupational exposure limit for formaldehyde based on irritation. J. Toxicol. Environ. Health 50(3): 217-263.

Porter JAH. (1975). Acute respiratory distress following formalin inhalation. Lancet 1:603-604.

Rudzki E, Rebandel P, Grzywa Z. (1989). Patch tests with occupational contactants in nurses, doctors and dentists. Contact Dermatitis 20:247-259.

Sneddon, I.B. (1968). Dermatitis in an intermittent haemodialysis unit. Br. med. J., 1: 183-184.

Solomons K, Cochrane JWC. (1984). Formaldehyde toxicity: Part 1. Occupational exposure and a report of 5 cases. S Afr Med J 66:101-102.

Solomons K, Cochrane JWC. (1984). Formaldehyde toxicity: Part 1. Occupational exposure and a report of 5 cases. S Afr Med J, 66:101-102.

Uba, G., et al. (1989). Prospective Study of Respiratory Effects of Formaldehyde among Healthy and Asthmatic Medical Students. Am. J. Ind. Med. 15: 91-101.

Weber-Tschopp A, Fisher T, Granjean E. (1977). Irritating effects of formaldehyde on men. Int Occup Environ Health. 39:207-218.

WHO (World Health Organization). (1989). Formaldehyde WHO Environmental Health Criteria , 89 (1989) 219 p

WHO (World Health Organization). (2002). Formaldehyde, Concise International Chemical Assessment Document 40. Geneva: World Health Organization

Wilson, JT Jr., M.D. (1987). Formaldehyde Exposure Following Urea Formaldehyde Insulation. Environmental Health and Safety News, University of Washington, v.26IUCLID Dateset. (2000). European Commission – European Chemicals Bureau. Year 2000 CD-ROM edition.

Agency for Toxic Substances and Disease Registry (1999): Toxicological Profile for Formaldehyde. U.S. Department of Health and Human Services.

Adams, D.O. et al. (1987). The Effect of Formaldehyde Exposure upon the Mononuclear Phagocyte System of Mice. Toxicology and Applied Pharmacology 88: 165-174. (NCEA)

Appelman, L.M. et al. (1988). One-year Inhalation Toxicity Study of Formaldehyde in Male Rats with a Damaged or Undamaged Nasal Mucosa. Journal of Applied Toxicology, 8(2): 85-90.

Arts, JH., Droge, S,C., Spanhaak, S. et al. (1997). Local lymph node activation and IgE responses in brown Norway and Wistar rats after dermal application of sensitizing and non-sensitizing chemicals. Toxicology 117:229-234.

Bartnik, F.G., Gloxhuber Chr and Zimmermann, V. (1985), Percutaneous Absorption of Formaldehyde in Rats. Toxicology Letters. v. 25. p. 167 - 172.

Basler, A., W. v. d. Hude and M. Scheutwinkel-Reich. (1985). "Formaldehyde-Induced Sister Chromatid Exchanges in vitro and the Influence of the Exogenous Metabolizing Systems S9 Mix and Primary Rat Hepatocytes." Arch Toxicol 58: 10-13.

Battelle, Pacific Northwest Laboratories. (1980). "Tracor Jitco Inhalation Carcinogenesis Bioassay: Repeated Dose Study Report on Formaldehyde."

Blackburn, G.R., Dooley, J, III., Schreiner, C.A. et al. (1991). Specific identification of formaldehyde-mediated mutagenicity using the mouse lymphoma L5178Y TK positive negative assay supplemented with formaldehyde dehydrogenase. In Vitro Toxicology 4:121-132.

Biagini, R.E., Moorman, W.J., Knecht, E.A. et al. (1989). Acute airway narrowing in monkeys from challenge with 2.5 ppm formaldehyde generated from formalin. Arch Environ Health 44:12-17.

Boja , J.W., Nielsen, J.A., Foldvary, E. et al. (1985). Acute Low-Level Formaldehyde Behavioural and Neurochemical Toxicity in the Rat. Prog Neuro-Psychopharmacol Biol Psychiat 9:671-674.

Buckley, L.A., Jiang, X.Z., James, R.A. et al. (1984). Respiratory tract lesions induced by sensory irritants at the RD50 concentration. Toxicol Appl Pharmacol 74:417-429.

Casanova-Schmitz, Mercedes., Thomas B. Starr and Henry D'A. Heck. (1984). Differentiation between Metabolic Incorporation and Covalent Binding in the Labeling of Macromolecules in the Rat Nasal Mucosa and Bone Marrow by Inhaled (14C)- and (3H) Formaldehyde. Toxicology and Applied Pharmacology 76: 26-44.

Casanova, Mercedes., Donald F. Deyom and Henry D'A. Heck. (1989). Covalent Binding of Inhaled Formaldehyde to DNA in the Nasal Mucosa of Fischer 344 Rats: Analysis of Formaldehyde and DNA by High-Performance Liquid Chromatography and Provisional Pharmacokinetic Interpretation. Fundamental and Applied Toxicology 12: 397-417.

Casanova, Mercedes. et al. (1991). Covalent Binding of Inhaled Formaldehyde to DNA in the Respiratory Tract of Rhesus Monkeys: Pharmacokinetics, Rat- to-Monkey Interspecies Scaling, and Extrapolation to Man. Fundamental and Applied Toxicology 17: 409-428.

Casanova, Mercedes. et al. (1994). DNA-Protein Cross-links and Cell Replication at Specific Sites in the Nose of F344 Rats Exposed Subchronically to Formaldehyde. Fundamental and Applied Toxicology 23: 525-536.

Cassee, F.R., Arts, J.H., Groten, J.P. et al. (1996). Sensory irritation to mixtures of formaldehyde, acrolein, and acetaldehyde in rats. Arch Toxicol 70:329-337.

Cassidy, S.L., K.M. Dix and T. Jenkins. (1983). Evaluation of a testicular sperm head counting technique using rats exposed to dimethoxyethyl phthalate (DMEP), glycerol a-monochlorohydrin (GMCH), epichlorohydrin (ECH), formaldehyde (FA), or methyl methanesulphonate (MMS). Arch. Toxicol. 53:71-78

Chang, J.C.F., W.H. Steinhagen, and S. Barrow. (1981). Effect of Single or Repeated Formaldehyde Exposure on Minute Volume of B6C3F1 Mice and F-344 Rats. Toxicology and Applied Pharmalcology. 61: 451-459.

Chang, J.C.F. et al. (1983). Nasal Cavity Deposition, Histopathology, and Cell Proliferation after Single or Repeated 18.59 mg/m3 formaldehyde for 6 epithelial cells, necrobiotic cells with Formaldehyde Exposures in B6C3F1 Mice and F-344 Rats. Toxicology and Applied Pharmacology, v. 68, p. 161-176.

Chang, J.C. and Barrow, C.S. (1984). Sensory irritation tolerance and cross-tolerance in F-344 rats exposed to chlorine or formaldehyde gas. Toxicol Appl Pharmacol 76:319-327.

Conolly R.B. et al. (2002): Dose response for formaldehyde- induced cytotoxicity in the human respiratory tract. Regul Toxicol Pharmacol. Feb;35(1):32-43.

Conolly, R.B. et al. (2003). Biologically Motivated Computational Modeling of Formaldehyde Carcinogenicity in the F344 Rat. Toxicol. Sci.75: 432–447.

Conolly, R.B. et al. (2004): Human respiratory tract cancer risks of inhaled formaldehyde:dose-response predictions derived from biologically-motivated computational modeling of a combined rodent and human dataset Toxicol Sci. Nov;82(1):279-96.

Connor, TH; Barrie, MD; Theiss, JC; et al. (1983) Mutagenicity of formalin in the Ames assay. Mutat Res 119:145–149.

Connor, TH; Theiss, JC; Hanna, HA; et al. (1985) Genotoxicity of organic chemicals frequently found in the air of mobile homes. Toxicol Lett 25:33–40.

Craft, T.R., E. Bermudez, and T.R. Skopek. (1987). Formaldehyde mutagenesis and formation of DNA-protein crosslinks in human lymphoblasts in vitro. Mutation Research 176: 147-155.

Dalbey, W.E. (1982). Formaldehyde and tumors in hamster respiratory tract. Toxicology. 24: 9-14.

Dean et al. (1984). Studies of Immune Function and Host Resistance in B6C3F1 Mice Exposed to Formaldehyde. Toxicology and Applied Pharmacology, v.72, p. 519-529.

Donovan, SM; Krahn, DF; Stewart, JA; et al. (1983) Mutagenic activities of formaldehyde (HCHO) and hexamethylphosphoramide (HMPA) in reverse and forward S*almonella typhimurium* mutation assays. Environ Mutagen 5:476.

Dubreuil, A., G. Bouley, J. Godin, and C. Boudène. (1976). Continuous inhalation of low-level doses of formaldehyde: Experimental study on the rat. Eur. J. Toxicol. 9:245-250.

DuPont, 7/28/80, Haskell Laboratory Report No. 581-80. Mouse Lymphoma L5178Y Cell TK Locus Assay for Mutagenicity; A Study with Formaldehyde.

Fontignie-Houbrechts, N. (1981). Genetic Effects of Formaldehyde in the Mouse. Mutation Research, v. 88, p. 109-114.

Frei, E; Pool, BL; Plesch, W; et al. (1984) Biochemical and biological properties of prospective N-nitrodialkylamine metabolites and their derivatives. IARC Sci Publ 57:491–497.

Gardner, R.J., Burgess, B.A. and Kennedy, G.L., Jr. (1985). Sensory irritation potential of selected nasal tumorigens in the rat. Food Chem Toxicol 23:87-92.

Graves, R.J., Trueman, P., Jones, S. et al. (1996). DNA sequence analysis of methylene chloride-induced HPRT mutations in Chinese hamster ovary cells: Comparison with the mutation spectrum obtained for 1,2-dibromoethane and formaldehyde. Mutagenesis 11:229-233.

Fujimaki, H., Kurokawa, Y., Kunugita, N. et al. (2004). Differential immunogenic and neurogenic inflammatory responses in an allergic mouse model exposed to low levels of formaldehyde. Toxicology 197:1-13.

Hauptmann, M; Lubin, JH; Stewart, PA; et al. (2003) Mortality from lymphohematopoietic malignancies among workers in formaldehyde industries. J Natl Cancer Inst 95:1615-1623.

Hauptmann, M; Lubin, JH; Stewart, PA; et al. (2004) Mortality from solid cancers among workers in formaldehyde industries. Amer J Epidemiology 159:1117-1130.

Heck, D.A., Henry, and Merccedes Casanova. (1987). Isotope Effects and Their Implications for the Covalent Binding of Inhaled (3H) and (14C) Formaldehyde in the Rat Nasal Mucosa. Toxicology and Applied Pharmacology 89: 122-134. .

Hester, et al. (2003). Formaldehyde-Induced Gene Expression in F344 Rat Nasal Respiratory Epithelium. Toxicology 187: 13-24.

Hilton et al. (1996). Experimental Assessment of the Sensitizing Properties of Formaldehyde. Food and Chemical Toxicology 34: 571-578.

Iversen, Olav Hilmar. (1986). Formaldehyde and Skin Carcinogenesis. Environ Int 12:541-544.

Iversen, Olav Hilmar. (1988). Formaldehyde and Skin Tumorigenesis. Environ Int 14:23-27.

Jakab, GJ. (1992). Relationship between carbon black particulate-bound formaldehyde, pulmonary antibacterial defenses, and alveolar macrophage phagocytosis. Inhal Toxicol 4:325-342.

Jeffcoat, A.R., Chasalow, F., Feldman, DB., Marr, H. (1983): Disposition of 14-C Formaldehyde after Topical Exposure to Rats, Guinea Pigs, and Monkeys. In: Gibson JE, ed. Formaldehyde Toxicity. Washington, D.C.: Hemisphere Publishing Corporation, 38-50.

Johannsen, F.R., Levinskas, G.J., Tegris, A.S. (1986). Effects of Formaldehyde in the Rat and Dog following Oral Exposure. Toxicology Letters 30:1-6.

Kamata, Eiichi. et al. (1997). Results of a 28-month Chronic Inhalation Toxicity Study of Formaldehyde in Male Fischer-344 Rats. The Journal of Toxicological Sciences 22(3): 239-254.

Kane, Laurel E. and Alarie, Yves. (1977). Sensory Irritation to Formaldehyde and Acrolein During Single and Repeated Exposures in Mice. American Industrial Hygiene Association Journal, v.38, p. 509-522.

Kimbell JS, Overton JH, Subramaniam RP, Schlosser PM, Morgan KT, Conolly RB, Miller FJ. (2001): Dosimetry modeling of inhaled formaldehyde: binning nasal flux predictions for quantitative risk assessment. Toxicol Sci. Nov;64(1):111-21.

Kligerman, A.D., Phelps, M.C., Erexson, G.L. (1984). Cytogenetic analysis of lymphocytes from rats following formaldehyde inhalation. Toxicol Lett 21:241-246. .

Krivanek, N.D., Chromey, N.C. and McAlack, J.W. (1983)."Skin initiation- promotion study with formaldehyde in CD-1 mice", E.I. du Pont de Nemours & Company, Inc. In: Formaldehyde: Toxicology, Epidemiology, and Mechanisms, Clary, J.J., J.E. Gibson, and R.S. Waritz, Eds., N.Y., Marcel Dekker, Inc.

Kulle, T.J. and Cooper, G.P. (1975). Effects of formaldehyde and ozone on the trigeminal nasal sensory system. Arch Environ Health 30:237-243.

Lee, Hye Kyung., Alarie, Yves and Karol, M.H. (1984). Induction of Formaldehyde Sensitivity in Guinea Pigs. Toxicology and Applied Pharmacology, v. 75, p.147-155.

Liber, H.L., Benforado, K.. Crosby, R.M. et al. (1989). Formaldehyde-induced and spontaneous alterations in human hprt DNA sequence and mRNA expression. Mutat Res 226:31-37.

Malek, F.A., Moritz, K.U. and Fanghanel, J. (2003a). Formaldehyde inhalation and open field behaviour in rats. Ind J Med Res 118:90-96.

Malek, F.A., Moritz, K-U. and Fanghaenel, J. (2003b). A study on specific behavioral effects of formaldehyde in the rat. J Exp Anim Sci 42:160-170.

Marnett, LJ; Hurd, HK; Hollstein, MC; et al. (1985) Naturally occurring carbonyl compounds are mutagens in salmonella tester strain TA104. Mutat Res 148(1–2):25–34.

Monticello et al. (1991). Regional Increases in Rat Nasal Epithelial Cell Proliferation following Acute and Subchronic Inhalation of Formaldehyde. Toxicology and Applied Pharmacology 111: 409-421.

Morgan, K. et al. (1986). Responses of the Nasal Mucociliary Apparatus of F-344 Rats to Formaldehyde Gas. Toxicology and Applied Pharmacology 82: 1-13.

Muller, W; Engelhart, G; Herbold, B; et al. (1993) Evaluation of mutagenicity testing with *Salmonella typhimurium* TA102 in three different laboratories. Environ Health Perspect 101(Suppl. 3):33–36.

Natarajan, A.T. et al. (1983). Evaluation of the mutagenicity of formaldehyde in mammalian cytogenics assays in vivo and vitro. Mutation Research 122: 355-360.

Odeigah, P.G.C. (1997). "Sperm Head Abnormalities and Dominant Lethal Effects of Formaldehyde in Albino Rats." Mutation Research 389: 141-148.

O'Donovan, MR; Mee, CD. (1993) Formaldehyde is a bacterial mutagen in a range of salmonella and escherichia indicator strains. Mutagenesis 8:577–581.

Oerstavik, D; Hongslo, JK. (1985) Mutagenicity of endodontic sealers. Biomaterials 6:129–132.

Ohtsuka, R., Shuto, Y., Fujie, H. et al. (1997). Response of respiratory epithelium of BN and F344 rats to formaldehyde inhalation. Exp Anim 46:279-286.

Ohtsuka, R., Shutoh, Y., Fujie, H. et al. (2003). Rat strain difference in histology and expression of Th1- and Th2-related cytokines in nasal mucosa after short-term formaldehyde inhalation. Exp Toxicol Pathol 54:287-291.

Overman, D.O. (1984). Absence of Embryotoxic Effects of Formaldehyde after Percutaneous Exposure in Hamsters. Toxicology Letters 24: 107-110.

Pitten, F.A., Kramer, A., Herrmann, K. et al. (2000). Formaldehyde neurotoxicity in animal experiments. Pathol Res Pract 196:193-198.

Riedel, F. et al. C.H.L. (1996). Formaldehyde Exposure Enhances Sensitization in the Guinea Pig. Allergy 51: 94–99.

Ross, WE; Shipley, N. (1980) Relationship between DNA damage and survival in formaldehyde-treated mouse cells. Mutat Res 79:277–283.

Ryden, E; Ekstrom, C; Hellmer, L; et al. (2000) Comparison of the sensitivities of *Salmonella typhimurium* strains TA102 and TA2638A to 16 mutagens. Mutagenesis 15:495–502.

Saillenfait, A.M. et al (1989). The effects of maternally inhaled formaldehyde on embryonal and foetal development in rats. Fd. Chem. Toxic. 27(8): 545-548.

Schlosser PM, Lilly PD, Conolly RB, Janszen DB, Kimbell JS: Benchmark dose risk assessment for formaldehyde using airflow modeling and a single-compartment, DNA-protein cross-link dosimetry model to estimate human equivalent doses. Risk Anal. 2003 Jun;23(3):473-87.

Schmid, E., Goggelmann, W. and Bauchinger, M. (1986). Formaldehyde-induced Cytotoxic, Genotoxic, and Mutagenic Response in Human Lymphocytes and Salmonella typhimurium. Mutagenesis vol. 1 no. 6 p. 427-431.

Spangler, F. and Ward, J.M. (1983). "Skin initiation/promotion study with formaldehyde in Sencar mice". Study location: Microbiological Associates (Bethesda, MD) in conjunction with NCI. In: Formaldehyde: Toxicology, Epidemiology, and Mechanisms, Clary, J.J., J.E. Gibson, and R.S. Waritz, Eds., N.Y., Marcel Dekker, Inc.

Subramaniam, R., Chen, C., Crump, K., Fox, J., Schlosser, PM., and White, P. (2007). Uncertainties in the CIIT 2-stage model for formaldehyde-induced nasal cancer in the F344 rat: a limited sensitivity analysis - I. *Risk Anal*. 27, 1237-54.

Steinhagen, W.H. and Barrow, C.S. (1984). Sensory irritation structure-activity study of inhaled aldehydes in B6C3F1 and Swiss-Webster mice. Toxicol Appl Pharmacol 72:495-503.

Takahashi et al. (1986). Effects of Ethanol, Potassium Metabisulfate, Formaldehyde, and Hydrogen Peroxide on Gastric Carcinogenesis in Rats after Initiation with N-methyl-N'nitro-N'nitrosoguanidine. Jap. J. Cancer Res. 77: 118-124.

Tarkowski, M. and Gorski, P. (1995). Increased IgE antiovalbumin level in mice exposed to formaldehyde. Int. Arch. Allergy Immunol. 106: 422–424.

Temcharoen, P., Thilly, W.G. (1983). Toxic and mutagenic effects of formaldehyde in Salmonella typhimurium. Mutat Res 119:89-93.

Til, H.P. et al. (1988). Evaluation of the Oral Toxicity of Acetaldehyde and Formaldehyde in a 4-week Drinking Water Study in Rats. Fd. Chem. Toxic. 26(5): 447-452.

Tobe, M., Kaneko, T., Uchida, Y. et al. (1985). Studies of the inhalation toxicity of formaldehyde. National Sanitary and Medical Laboratory Service (Japan). p. 1-94.

Tsubone, H. and Kawata, M. (1991). Stimulation to the trigeminal afferent nerve of the nose by formaldehyde, acrolein, and acetaldehyde gases. Inhal Toxicol 3:211-222.

Valencia, R., Mason, J.M. and Zimmering, S. (1989). Chemical Mutagenesis Testing in Drosophila. VI. Interlaboratory Comparison of Mutagenicity Tests After Treatment of Larvae. Environmental and Molecular Mutagenesis, v. 14, p. 238-244.

Vargova, M., Wagnerova, J., Liskova, A. et al. (1993). Subacute immunotoxicity study of formaldehyde in male rats. Drug Chem Toxicol 16:255-275.

Woutersen, R.A. et al. (1987). Subchronic (13-week) Inhalation Toxicity Study of Formaldehyde in Rats. Journal of Applied Toxicology, 7(1): 43-49.

Xu, B., Aoyama, K., Takeuchi, M. et al. (2002). Expression of cytokine mRNAs in mice cutaneously exposed to formaldehyde. Immunol Lett 84:49-55.

Zielenska, M; Guttenplan, JB. (1988) Mutagenic activity and specificity of N-nitrosomethylaniline and N-nitrosodiphenylamine in salmonella. Mutat Res 202(1):269–276.

2. Website References

Citation

Assessments of the reproductive and developmental toxicity of formaldehyde conducted by the Australian government (www.nicnas.gov.au) as well as the Agency for Toxic Substances and Disease Registry (ATSDR, 1999)support this conclusion.

EPA is currently completing a new IRIS assessment that will include a cancer unit risk value for formaldehyde; the reassessment is scheduled to start internal peer review in May 2008 and begin independent external peer review in January 2009 (http://cfpub.epa.gov/ncea/iristrac/index.cfm?fuseaction =view Chemical.showChemical&sw_id=1031). EPA anticipates that the peer review of the formaldehyde assessment will not be finished before EPA completes the reregistration process for formaldehyde pesticidal uses, scheduled to conclude in September 2008.

The EPA's Consumer Exposure Module (CEM) was used to estimate air concentrations resulting from the use of laundry detergent preserved with formaldehyde. Detailed information and the executable model can be downloaded from http://www.epa.gov/opptintr/exposure.

3. Other Supporting Documents

Citation

ASHRAE, 1989. Ventilation for Acceptable Indoor Air Quality, American Society of Heating Refrigerating and Air Conditioning Engineers, 1989.

ASRC, 2005. Formaldehyde Smart Meeting, August 9, 2005, Minutes Prepared by Eric Brewer of ASRC Aerospace.

Jacobson, Larry. 2005. Professor and Extension Engineer at University of Minnesota.

Kline, 2000. Specialty Biocide North America 2000, Kline and Company, Inc.

NIOSH, 1990. Health Hazard Evaluation of Buckeye Hills Career Center (HETA 88-153-2072), NIOSH, October 1990.

NIOSH, 1997. Pocket Guide to Chemical Hazards, DHHS (NIOSH Publication No. 97-140)

Olcrest, 1999. Paraformaldehyde Sterilant Use in Vocational High School Program, Robert Olcrest, Brujos Scientific Inc., Baltimore, Maryland. Published in Applied Occupational and Environmental Hygiene, Volume 14: 391-396, 1999

USDA, 1999. Crop Profile for Poultry (Broilers) in California

USDA, 2000. Crop Profile for Eggs in California

USDA, 2002. Crop Profile for Poultry in Florida

US EPA, 1997a. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

US EPA, 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., US EPA, to Julie Fairfax,

US EPA, 2008. Incident Reports Associated with Formaldehyde. Jonathen Chen Ph.D.,

US EPA, 2008. Formaldehyde - Report of the Antimicrobials Division Toxicity Endpoint Selection Committee (ADTC),

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See the Formaldahyde / Paraformaldahyde RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date for:

Formaldahyde / Paraformaldahyde (0556)

Appendix G. Batching of Formaldahyde / ParaformaldahydeProducts for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency intends to complete a Batching Memo at a later date

Appendix H. List of All Registrants Sent the Data Call-In

The Agency intends to issue a Data Call-In at a later date to the following registrants:

Baker Petrolite Corporation
12645 West Port Airport Blvd
Sugarland, Texas 77478

Champion Technologies, Inc.
3185 Madison Highway, PO Box 5126
Valdosta Georgia 316035126

Protexall Products, Inc.
402 Integrated Court
Debary, Florida 32713

Noble Pine Products Co.
PO Box 41 Centuck Stat
Yonkers, New York, 10710

Hess & Clark Inc.
110 Hopkins Drive
Randolph, Wisconsin 539561316

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/ .

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program—Storage and Disposal Statements

    b. 84-1 Clarification of Label Improvement Program

    c. 86-5 Standard Format for Data Submitted under FIFRA

    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

    a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

    b. EPA Form No. 8570-4, Confidential Statement of Formula

    c. EPA Form No. 8570-27, Formulator's Exemption Statement

    d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

    e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158,Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: http://npic.orst.edu .

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.