UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

April 26, 2006

MEMORANDUM:

Subject: Glutaraldehyde: Occupational and Residential Exposure Assessment for the Registration Eligibility Decision (RED)

To: Tim McMahon Ph.D., Toxicologist
Antimicrobials Division

From: Timothy C. Dole, CIH, Industrial Hygienist
Reregistration Branch I (RRB1)
Health Effects Division (7509C)

Thru: Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch I (RRB1)
Health Effects Division (7509C)

DP Barcode: D324565

Chemical Name:	PC Code:	CAS Registry No.	Abbreviation
Glutaraldehyde	043901	111-30-8	GA

MRIDs: 44181201, 45369501
46682201, 46682202, 46682204, 46682206, 46682207

MAY 30 2006

MAY 24 2006

TABLE OF CONTENTS

EXECUTIVE SUMMARY .....
1.0 INTRODUCTION .....
1.1 Purpose .....
1.2 Criteria for Conducting Assessments .....
1.3 Chemical Identification .....
1.4 Physical/Chemical Properties .....

2.0 USE INFORMATION .....
2.1 Formulation Types and Percent Active Ingredient .....
2.2 Summary of Registered Uses .....
2.3 Summary of Use Data

3.0 INCIDENT REPORT

4.0 SUMMARY OF TOXICITY DATA .....
4.1 Acute Toxicity .....
4.2 Summary of Toxicity Endpoints .....
4.3 FQPA Considerations .....

5.0 RESIDENTIAL EXPOSURE ASSESSMENT .....
5.1 Residential Handler Exposures .....
5.1.1 Paint Handling Inhalation Exposure .....
5.1.2 Laundry Detergent Handling Inhalation Exposure .....
5.1.3 Treated Products Dermal Exposure .....
5.2 Residential Post-application Exposure .....
5.2.1 Paint Inhalation Exposures .....
5.3 Data Limitations/Uncertainties .....

6.0 OCCUPATIONAL EXPOSURE ASSESSMENT .....
6.1 Occupational Handler Exposures .....
6.1.1 General Handler Inhalation Exposures .....
6.1.2 Professional Painter Inhalation Exposures .....
6.1.3 Medical Hard Surface Cleaning Exposures
6.2 Occupational Post-application Exposures .....
6.2.1 Poultry House Fogging Inhalation Exposures .....
6.2.2 Metal Working Fluids Dermal Exposures .....
6.5 Data Limitations/Uncertainties .....

7.0 RECOMMENDATIONS TO MITIGATE RISKS OF CONCERN

8.0 REFERENCES .....

APPENDIX A: Label Use Patterns
APPENDIX B: Glutaraldehyde ORE Assessment Modeling Runs and Spreadsheets .....

EXECUTIVE SUMMARY

This document is the Occupational and Residential Exposure Chapter of the Reregistration Eligibility Decision (RED) for glutaraldehyde (GA). It addresses the potential risks to humans that result from the use of GA in occupational and residential settings.

Glutaraldehyde Use Summary

Glutaraldehyde (GA) is an active ingredient in numerous disinfecting products and is also used as a materials preservative. GA is used for slimicide treatment of cooling towers, industrial process water, metal working fluids and oil field muds. As a materials preservative, GA is used in paints, laundry detergents and paper. Medical uses of GA include RTU sprays and wipes that are used to clean non-critical surfaces and medical waste treatment products that are used to disinfect medical waste such as fluid in suction canisters and general medical waste. GA is also widely used as a sterilant and high-level disinfectant for endoscopy equipment, however, that use is not regulated by the EPA because it is under the purview of the FDA as discussed in PR Notice 98-2.

Incident Report

According to the incident report (US EPA 2006), 267 cases involving GA were reported in the OPP incident data system. The incident report does not indicate; however, if these incidents involved the medical uses such as instrument sterilization or the non-medical uses such as animal housing or cooling water treatment. The incident report also lists 403 incidents that were reported in the California Pesticide Surveillance Program for the years 1982 to 2003, and 398 of these incidents involved medical uses of GA. There were 5 incidents that involved non-medical uses. The low usage of GA in California for non-medical applications may account for the small number of incidents associated with non-medical uses. There have also been a number of incidents reported in the literature and most of these were associated with medical uses.

Glutaraldeyde Toxicity

Acute toxicity testing indicated that GA is a Toxicity Category I (i.e. severe) eye and skin irritant and it is a skin sensitizer. Dermal toxicity studies indicate that skin corrosion effects were observed with a NOAEL of 50 mg/kg/day (2.5% glutaraldehyde), while systemic effects did not occur at the 150 mg/kg/day which was the highest dose tested.

Inhalation toxicity studies indicated histopathology of the upper respiratory tract and inflammation of the lower respiratory tract and the effects were seen at progressively lower doses depending upon the duration of the study. The NOAELs and LOAELs were converted to Human Equivalent Concentrations (HECs) using the regional deposited dose ratio method outlined in the Agencies RfC guidance. The HECs included a correction for exposure time in the animal study (6 hours per day) versus the exposure times expected in humans (8 hours per day for occupational exposure and 24 hours day for residential exposure). The HECs were then converted to 'Reference Concentrations' (RfCs) by the dividing the HEC by the uncertainty factor. The short- and intermediate- term RfCs used an uncertainty factor of 30X which includes 3X for inter-species extrapolation and 10X for intra-species variation. The

long term RfCs used an uncertainty factor of 300X which includes 3X for inter-species extrapolation, 10X for intra-species variation and 10X for the use of a LOAEL. The RfCs in units of parts per billion (ppb) are listed below:

Exposure Duration	Occupational RfC	Residential RfC
Short Term	0.32 ppb	0.12 ppb
Intermediate Term	0.24 ppb	0.073 ppb
Long Term	0.015 ppb	0.005 ppb

The American Conference of Governmental Hygienists (ACGIH) has evaluated the GA literature and recommended a threshold limit value (TLV) of 0.2 mg/m^3(50 ppb) as a ceiling value. A ceiling value is an exposure limit that should not be exceeded at any time during the workday and is normally assessed as a 15 minute exposure. Although the ACGIH did review the same animal toxicity studies that were used by EPA, the ACGIH chose a ceiling value because the literature indicated that short term exposures at or below 100 ppb have resulted in symptoms of nose, throat, skin and eye irritation among medical workers using GA.

Residential Exposure Assessment

All of the GA products appear to be intended for use only in industrial or medical areas; however, the residential population may be exposed to household items such as laundry detergents and paints that have been treated with GA as a material preservative and emissions from cooling towers that have been treated with GA as a slimicide.

Residential Handler Exposures

Residential handler inhalation exposures were assessed for use of paint and laundry detergent treated with 100 ppm or 1000 ppm GA as a preservative. The painter inhalation exposures were assessed using the EPA's Wall Paint Exposure Model (WPEM) and laundry detergent inhalation exposures were assessed using the EPA's Consumer Exposure Module (CEM). Both the paint and laundry detergent scenarios were assessed as short term exposures because the uses occur intermittently. At the minimum treatment rate (100 ppm) the 24 hour average air concentration for the painter is 2.2 ppb which exceeds the RfC of 0.12 ppb and the paint user inhalation exposures are of concern. For the handlers of laundry detergent treated at 100 ppm, the 24 hour average air concentration of 0.26 ppb also exceeds the RfC.

Residential handler dermal exposures were assessed by comparing the concentration in the paints and the laundry detergents with the concentrations used in the dermal toxicity studies. The dermal exposures are of concern at the high treatment rate of 1000 ppm (0.1 percent) because the Margin of Exposure (MOE) of 25 is less than the target MOE of 100. The dermal exposures are not of concern when the treatment rate is 250 ppm (0.025 percent) because the MOE is equal to 100.

Residential Post Application Exposures

Residential postapplication exposure scenarios include inhalation exposures from paints and cooling tower emissions. Typically, paints used in a residential setting result in short term exposure durations (1 to 30 days) while cooling tower emissions can result in long term exposures. The WPEM model was used to estimate air concentrations resulting from the use of paint preserved with GA with the assumption that the resident is located in a non-painted part of the house while a bedroom is being painted by a professional painter. The 24 hour average air concentration of 3.7 ppb exceeds the short term RfC of 0.12 ppb when paint treated at the minimum rate of 100 ppm is used. Cooling tower potential emissions were evaluated using a proprietary model (CT-EVAP) which was validated with air sampling at a representative cooling tower. The results of the modeling and air sampling suggest that GA air concentrations exceed the long term RfC of 0.005 ppb. It is important to note; however, that the CT-EVAP model was validated with only a limited set of air concentration data that were collected over a short time period fairly close to the source.

Occupational Exposure Assessment

Occupational Handler Exposures

There are several occupational handler exposure scenarios that involve GA products. These scenarios either involve the manual or automatic addition of GA products to industrial processes or they involve the application of dilution solutions of GA to interior surfaces or spaces such a medical hard surfaces or poultry houses. Because GA has a relatively high vapor pressure (0.1 mm Hg at 50% solution concentration), the unit exposure data from PHED and CMA are not applicable because these data are based upon chemicals that have a much lower vapor pressure (less than 1.0×10^{-4} mm Hg). When the vapor pressure is less than 1.0×10^{-4}, chemicals are airborne primarily as aerosols, while at a higher vapor pressure, chemicals are airborne primarily as vapors. In addition, the toxicology endpoints for GA were derived from inhalation studies where the test animals were exposed to GA as a vapor. Instead of calculating exposures using the CMA or PHED data, GA air sampling data were reviewed to determine if GA exposures exceed the RfC. Most of the available exposure data are from short term samples of approximately 15 minutes in duration and they were taken as a comparison to the ACGIH TLV of 50 ppb. Although many of the short term samples exceeded the RfC of 0.32 ppb, these samples are not comparable to the RfC because the un-sampled periods probably had lower exposures than the sampled period (i.e. they do not represent the 8 hour TWA). A few of the drumming samples reported by Dow Chemical were taken over a full shift and the results of these samples ranged from 10 to 170 ppb. All of these samples exceeded the short term RfC of 0.32 ppb and some exceed the TLV of 50 ppb.

There are three products which are used to clean non-critical hard surfaces in medical clinics, dental clinics and veterinary offices. The CEM model was used to estimate air concentrations resulting from these uses. Input values included a weight fraction of 0.00275 and ventilation rates of 0.45 and 4 air changes per hour. Since medical surface cleaners can be used on a year round basis, only long term exposures were assessed. The 8 hour average air concentrations exceed the long term RfC of 0.063 ppb at both the minimum and maximum

ventilation rates and are of concern. The daily peak exposure of 130 ppb at the minimum ventilation rate is also of concern because it exceeds the ACGIH TLV of 50 ppb.

Occupational Post Application Exposures

Post application GA inhalation exposures were assessed for professional painters using paint preserved with GA and for workers entering poultry houses after fogging with GA. Post application dermal exposures were also assessed for machinists using metal working fluids treated with GA.

Professional painter inhalation exposure to GA vapors was assessed using the WPEM Model with the standard assumption that two professional painters would paint an entire 7350 ft^3 apartment in a work day. Since professional painters can paint indoors on a year round basis, only long term exposures were assessed. The WPEM calculations indicated that the daily average GA air concentration of 54 ppb exceeded the long term RfC of 0.015 ppb at the low treatment rate, therefore, the inhalation exposures are of concern. Inhalation exposures to GA following poultry house fogging were assessed using the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2). The initial concentration of 25 ppm was based upon the parameters listed in the Virocide Label (71355-1) and it was assumed that the ventilation rate was 4 air changes per hour. The MCCEM calculations indicate that the air concentrations declined to the TLV of 50 ppb in 95 minutes and to the RfC of 0.32 ppb in 170 minutes.

Dermal exposures to GA in metal working fluids were assessed by comparing the concentrations in the metal working fluids with the concentrations used in the dermal toxicity studies. The dermal exposures are of concern at the high application rate of 270 ppm (0.027 percent) because the MOE of 92 is slightly less than the target MOE of 100. The dermal exposures are not of concern at the low application rate of 36 ppm (0.0036 percent) because the MOE exceeds 100.

Recommendations to Mitigate Risks of Concern

To mitigate the residential risks arising from the use of glutaraldehyde treated paint or laundry detergent it is recommended that the treatment rates be reduced. To mitigate occupational risks of concern, GA should be only be used with appropriate work practices and engineering controls such that peak exposures do not exceed the ACGIH TLV and average daily exposures do not exceed the relevant RfCs. This can be accomplished by one or more of the following:

- The open pouring of GA solutions should be minimized.
- Automatic addition systems that minimize operator exposure to the concentrated product should be used when handling larger amounts of GA. If this is not feasible then local exhaust ventilation should be used to reduce GA exposure.
- Fogging of poultry houses should only be done in such a way that the operator is outside the poultry house when applying the fog.
- GA treated paint should only be used in well ventilated areas.
- GA hard surface cleaning products should only be used in areas with very good general ventilation.

1.0 INTRODUCTION

1.1 Purpose

In this document, the Health Effects Division (HED) presents its review of the potential human health effects of occupational and residential exposure to glutaraldehyde. This information is for use in EPA's development of the Registration Eligibility Decision (RED) for glutaraldehyde.

1.2 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For glutaraldehyde, both criteria are met.

1.3 Chemical Identification

This assessment is for glutaraldehyde which shall be identified as GA throughout the remainder of this document. Glutaraldehyde (GA) has a CAS number of 111-30-8, a PC Code of 043901 and a molecular formula of $C_5H_8O_2$.

1.4 Physical/Chemical Properties

The physical and chemical properties of GA are listed in Table 1.

Table 1 - Physical and Chemical Properties of GA

	Parameter	Source
Molecular Weight	100.1	Product Chemistry Data[1]
Color	Colorless	Product Chemistry Data[1]
Physical State	Liquid at about 7 F	Product Chemistry Data[1]
Specific Gravity	1.13 at 20 C	Product Chemistry Data[1]
Dissociation Constant	n/a	Product Chemistry Data[1]
pH	3.7 to 4.5	Product Chemistry Data[1]
Stability	Stable at proper conditions	Product Chemistry Data[1]
Melting Point	-6 C	Product Chemistry Data[1]
Boiling Point	100.5 C	Product Chemistry Data[1]
Water Solubility	167 gram/liter	Product Chemistry Data[1]
K_{ow}	0.66	Product Chemistry Data[1]
Vapor Pressure (1 torr = 1 mm Hg)	0.102 torr @ 20 C (50% solution) 0.003 torr @ 20 C (2% solution)	ACGIH[2]

1. Data Evaluation Records (DER) for Product Chemistry of Glutaraldehyde, A. Najm Shamim, 4/12/05
2. Documentation of Glutaraldehyde TLV, ACGIH 2001.

2.0 USE INFORMATION

2.1 Formulation Types and Percent Active Ingredient

According to OPPIN, as of 4/21/2006, there are 62 products containing GA as the active ingredient (a.i.). These products are formulated primarily as soluble concentrates with GA concentrations that range from 4 to 50%. There are also two RTU spray products, one RTU wipe product and two RTU encapsulant products. Concentrations of GA in the RTU products range from 0.275% to 10.72%.

2.2 Summary of Registered Uses

GA is an active ingredient in numerous disinfecting products and is also used as a materials preservative. It has been registered with EPA as a pesticide since 1963. A summary of uses which is based upon the smart meeting (Dow, 2005) is given in Table 2 and a more detailed listing to include specific registration numbers is included in Appendix A. GA is used for slimicide treatment of cooling towers, industrial process water, metal working fluids and oil field muds. As a materials preservative, GA is used in paints, laundry detergents and paper. Medical uses of GA include RTU sprays and wipes that are used to clean non-critical surfaces and medical waste treatment products that are used to disinfect medical waste such as fluid in suction canisters (46781-10) and general medical waste (71814-1). GA is also widely used to cold sterilize endoscopy equipment, however, that use is not included on any of the EPA labels because liquid chemical sterilant products used on critical or semi-critical devices are now regulated by the FDA as discussed in Pesticide Registration (PR) Notice 98-2.

Table 2 – Summary of GA Label Use Patterns

Use Category	Use Sites	Application Rate[A]	Addition Method
Process and Waste Water	Air Washers, Recirc and Once thru cooling, Service and Aux water	20 to 100 ppm	Open and Automatic
	Waste Water Beet Sugar	225 to 1125 ppm 15 to 250 ppm	Automatic
Pulp and Paper	Process Water Slurries and Coatings	50 to 750 ppm 50 to 300 ppm	Automatic
Fluids Preservation	Heat Transfer Metal Working Water Based Conveyor	20 to 100 ppm 36 to 270 ppm 50 to 300 ppm	Open and Automatic
Other Preservation	Reverse Osmosis General Preservative Use Preservative for Concentrates Concrete Admixtures	0.1 to 1.0% 100 to 1000 ppm 100 to 1000 ppm 0.1 to 0.4%	Open and Automatic
Oil Field	Water Floods Drilling and workover fluids Packer fluids Pipelines Storage Wells Pipeline pigging Hydro-testing	10 to 2500 ppm 25 to 500 ppm 25 to 300 ppm 250 to 2500 ppm 250 to 2500 ppm 500 to 5000 ppm 50 to 2000 ppm	Open and Automatic
Animal and Poultry Housing	Mopping Spraying Fogging	0.1 to 0.25 %	Open Pour and Hand Held Application

Table 2 – Summary of GA Label Use Patterns			
Use Category	Use Sites	Application Rate[A]	Addition Method
Medical	Surface Treatment Spray	0.275%	RTU
	Surface Treatment Wipe	0.275%	RTU
	Medical Waste Treatment [B]	9.6%	RTU
	Medical Waste Treatment [C]	7.8%	RTU

A. The label registration numbers for each application rate are given in Appendix A.
B. Is a RTU suction canister used to collect blood and other fluids discharged from suction systems.
C. Is used in a container system used to collect general medical waste.

2.3 Summary of Use Data

According to the National Occupational Exposure Survey (NIOSH, 1983) there were 260,000 to 380,000 workers exposed to GA. Most of these workers (320,000) were in the health services industry. These data are shown in Table 3.

Table 3 - Number of Workers and Facilities Reporting Glutaraldehyde		
Industry	Number of Workers	Number of Facilities
Agricultural services	570-3200	1-680
Oil and gas extraction	220-2500	1-120
Textile mill products	1-49	1-49
Paper and allied products	470-2600	1-250
Printing, publishing and allied industries	20000 (3700)[1]	190-2100
Chemicals and allied products	190-2170	1-480
Industrial and commercial machinery	1-140	1-66
Electrical equipment and components	1-130	1-58
Transportation Equipment	1-550	1-58
Measuring equipment and photographic, medical and optical goods	1-650	1-230
Air transport	1-290	1-26
Whole trade - non-durable goods	850-4800	1-410
Personal services	15000 (3000)[1]	740-4200
Business services	2130-7140	150-1700
Health services	320,000 (25,000)[1]	1800-6000
TOTAL	260,000 - 380,000	5100 -8200

[1]Standard error

According to a risk assessment published by the Commonwealth of Australia (NICNAS, 1994), the estimated distribution of GA in end use products in Australia was 55% in cold disinfectant products, 20% in Xray film processing, 5% in animal housing, 10% in water treatment, 5% in tanning and 5% in other uses including preservative/general biocide.

The Crop Profile for Poultry in Florida (USDA, 2002) indicates that GA was the 6th most used disinfectant on farms that reported pesticide use. It was used on 9% of the farms, while the most commonly used disinfectant (Clorox) was used on 53% of the farms. The Crop Profile for Poultry (Broilers) in California (USDA, 1999) indicates that GA was used by 10% of the growers in 1998.

The Vermont Agency of Agricultural Food and Markets indicates that GA usage in cooling towers ranked 9th in 2003 with 2,900 lbs used. The number one, two and three chemicals were dazomet (113,000 lbs), sodium O-phenyphenate (96,000 lbs) and dibromononitrilopropionamide (34,000 lbs).

According to the California Department of Pesticide Regulation (DPR), 240 to 6700 lbs of glutaraldehyde were used per year on various sites as shown in Table 4.

Table 4 - Pounds of Glutaraldehyde Used per Year in California

Year	2004	2003	2002	2001	2000	1999	1998	1997
Animal Premise	760	1100	210	164	23	25	2	16
Landscape Maintenance	452	590	99	6	8	None	None	15
Poultry and Turkey	2.4	None	27	44	None	2	11	3
Structural Pest Control	719	19	None	8	None	None	4	None
Water (Industrial + Area)	4800	46	28	20	1400	180	590	370
Total	6700	1800	370	240	1400	250	610	400

Source: California Department of Pesticide Regulation Pesticide Use Database

3.0 Incident Report

An incident report has been prepared for GA (US EPA, 2006a). According to this report, 267 cases involving GA were reported in the OPP Incident data system, however, the incident report does not indicate if these incidents involved the medical uses such as instrument sterilization or the non-medical uses such as animal housing or cooling water treatment. The incident report also lists 403 incidents that were reported in the California Pesticide Surveillance Program for the years 1982 to 2003, and 398 of these incidents involved medical uses of GA. There were 5 incidents that involved non-medical uses and these are listed in Table 5. The low usage of GA in California for non-medical uses (see Table 4) may account for the small number of incidents associated with non-medical uses. There have also been a number of incidents reported in the literature and most of these were associated with medical uses.

The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, and dizziness. There is evidence as well that glutaraldehyde can cause occupational asthma. Most of the dermal incidences are related to irritation and/or allergic type reaction. The most common symptoms were skin irritation/burning, rash, itching, and skin discoloration. Eye pain, burning of eyes, conjunctivitis, blurred vision, and acute inflammation are the primary symptoms associated with ocular exposure incidents.

Table 5 - Non-Medical Glutaraldehyde Incidents Reported by California DPR				
No.	Year	Relation-ship	Medical Description	Description
6	1987	Definite[A]	MILD CONJUNCTIVITIS OF LEFT EYE	WORKER WAS LOADING GLUTARALDEHYDE FROM A STORAGE TANK TO HIS TRUCK TO DISINFECT OIL PIPE LINES LATER. DURING THE TRANSFER, SOME OF THE CHEMICAL SPLASHED INTO HIS EYE. NO INDICATION IS GIVEN ABOUT PROTECTIVE EQUIPMENT.
13	1988	Definite	CONJUNCTIVAL IRRITATION	WORKER WAS FILLING GALLON CONTAINERS FROM 55 GALLON DRUM AND MATERIAL SPLASHED IN EYE. NOT WEARING PROVIDED GOGGLES. DIAGNOSIS- MILD CONJUNCTIVAL IRRITATION.
47	1989	Possible	EYE IRRITATION	WORKER WAS ADDING A MICROBIOCIDE TO A COOLING TOWER WHEN THE SOLUTION SPLASHED BACK INTO HIS FACE. HE WAS WEARING SAFETY GLASSES AND DIDN'T THINK THE MATERIAL ENTERED HIS EYE. HE WAS ALSO WORKING WITH ACID AND THOUGHT THE VAPORS MAY HAVE IRRITATED HIS EYE
65	1990	Probable[B]	RASH	AFTER APPLYING MATERIAL TO INCUBATORS, WITHOUT WEARING GLOVES THAT WERE FURNISHED, THE WORKER DEVELOPED A RASH. WORKER WAS ALREADY WEARING GLOVES AT TIME OF INVESTIGATION.
300	1997	Definite	MILD IRRITATION OF THE LEFT EYE.	WHILE CONDUCTING A ROUTINE INSPECTION OF A COOLING TOWER'S BIOCIDE LINE, A WORKER NOTICED SOME TAPE ON THE LINE. WHEN HE REMOVED THE TAPE, SOME BIOCIDE CAME OUT OF A CRACK IN THE LINE & GOT INTO HIS LEFT EYE. HE IMMEDIATELY FLUSHED THE EYE WITH WATER.
A. Definite - Both physical and medical evidence document exposure and consequent health effects. B. Probable - Limited or circumstantial evidence supports a relationship to pesticide exposure				

4.0 SUMMARY OF TOXICITY DATA

4.1 Acute Toxicity

The results of acute toxicity testing are listed in Table 6. Glutaraldehyde is a severe eye and skin irritant and it is a skin sensitizer.

Table 6 - Acute Toxicity of Glutaraldehyde				
Guideline No.	Study Type	MRID	Result	Toxicity Category
870.1100 870.1100	Acute oral Acute oral	011706-01 016437	LD50 = 360 mg/kg (M) LD50 = 420 mg/kg (F) LD50 = 460 mg/kg (combined)	II
870.1200	Acute dermal	446916-06	LD50 > 2000 mg/kg	III
870.1300	Acute inhalation	000602-75	LC50 >4.16 mg/L	IV
870.2400	Primary Eye Irritation	001170-66	Corrosive at high concentrations (i.e. 50%)	I
870.2500	Primary Skin Irritation	001170-61	Corrosive	I
870.2600	Dermal sensitization	---	Skin sensitizer	---

4.2 Summary of Toxicity Endpoints

EPA Endpoints

The toxicological endpoints for Glutaraldehyde that were used for this assessment are summarized in Table 7 and they were selected by the Antimicrobial Division Toxicity Endpoint Selection Committee (US EPA, 2006b).

The dermal toxicity endpoints were selected from a dermal toxicity study in which 2 ml/kg aliquots of aqueous solutions of 0%, 2.5%, 5% and 7.5% glutaraldehyde were applied to 2 x 2 inch areas on rats. This equates to 40 ul/cm^2 if it is assumed that the rats weighed 0.2 kg. Skin corrosion effects were observed with a NOAEL of 50 mg/kg/day (2.5% glutaraldehyde), while systemic effects did not occur at the maximum dose of 150 mg/kg/day (7.5% glutaraldehyde).

Inhalation toxicity studies indicated histopathology of the upper respiratory tract and inflammation of the lower respiratory tract and the effects were seen at progressively lower doses depending upon the duration of the study. The NOAELs and LOAELs were converted to Human Equivalent Concentrations (HECs) using the regional deposited dose ratio method outlined in the Agencies RfC guidance. The HECs included a correction for exposure time in the animal study (6 hours per day) versus the exposures times expected in humans (8 hours per day for occupational exposure and 24 hours day for residential exposure). The HECs were then converted to 'Reference Concentrations' (RfCs) by the dividing the HEC by the uncertainty factor. The short and intermediate term RfCs used an uncertainty factor of 30X which includes 3X for inter-species extrapolation and 10X for intra-species variation. The 3X factor was used for inter-species extrapolation instead of the traditional 10X factor because the conversion to an HEC reduced the inter-species uncertainty. The long term RfCs used an uncertainty factor of 300X which includes 3X for inter-species extrapolation, 10X for intra-species variation and 10X for the use of a LOAEL.

Table 7 – Glutaraldehyde Toxicological Endpoints Used for ORE Assessment

Exposure Scenario	Dose Used in Risk Assessment	UF	Study and Toxicological Effects
Dermal Exposures			
Short Term	Irritation NOAEL = 50 mg/kg/day (2.5% percent a.i.)	100	Rat 28 day dermal toxicity study (MRID 432591 - 01). LOAEL = 100 mg/kg/day (5.0% a.i.) based upon erythema, edema and skin lesions.
Intermediate Term	N/A	N/A	N/A
Long Term	N/A	N/A	N/A
Inhalation Exposures			
Short Term Occupational (8 hours/day)	NOAEL = 0.7 mg/m^3 HEC_{occ} = 0.041 mg/m^3 'RfC_{occ}' = 0.0013 mg/m^3 (0.32 ppb*)	30	Two-week inhalation toxicity study in rats and mice (NIH pub 93-3348). LOAEL = 2.0 mg/m^3 based upon histo-pathological alterations of the nasal passages, larynx, trachea and lung.
Short Term Residential (24 hours/day)	NOAEL = 0.7 mg/m^3 HEC_{res} = 0.014 mg/m^3 'RfC_{res}' = 0.0005 mg/m^3 (0.12 ppb*)	30	Same as above.
Intermediate Term Occupational (8 hours/day)	NOAEL = 0.51 mg/m^3 HEC_{occ} = 0.03 mg/m^3 'RfC_{occ}' = 0.001 mg/m^3 (0.24 ppb*)	30	Thirteen week inhalation toxicity study in rats and mice (NIH pub 93-3348). LOAEL = 1.02 mg/m^3 based upon histo-pathological changes of the nasal and respiratory tract epithelium.
Intermediate Term Residential (24 hours/day)	NOAEL = 0.51 mg/m^3 HEC_{res} = 0.01 mg/m^3 'RfC_{res}' = 0.0003 mg/m^3 (0.073 ppb*)	30	Same as above.

Table 7 – Glutaraldehyde Toxicological Endpoints Used for ORE Assessment			
Exposure Scenario	Dose Used in Risk Assessment	UF	Study and Toxicological Effects
Long Term Occupational (8 hours/day)	LOAEL = 0.26 mg/m^3 HEC_{occ} = 0.019 mg/m^3 'RfC_{occ}' = 0.00006 mg/m^3 (0.015 ppb*)	300	Two -Year inhalation toxicity study in rats and mice (MRID 448422-02). LOAEL = 0.26 mg/m^3 based upon squamous epithelial hyperplasia/inflammation and turbinate necrosis.
Long Term Residential (24 hours/day)	LOAEL = 0.26 mg/m^3 HEC_{res} = 0.004 mg/m^3 'RfC_{res}' = 0.00002 mg/m^3 (0.005 ppb*)	300	Same as above
* Unit Conversion: ppb = (mg/m^3 x 24.45 x 1000 ug/mg) / mw. For glutaraldehyde: 1 ppb = 0.00409 mg/m^3			

Comparison to Other Endpoints

The American Conference of Governmental Hygienists (ACGIH) has evaluated the GA literature and recommended a threshold limit value (TLV) of 0.2 mg/m^3 (50 ppb) as a ceiling value. A ceiling value is an exposure limit that should not be exceeded at any time during the workday and is normally assessed as a 15 minute exposure. Although the ACGIH did review the same animal toxicity studies that were used by EPA, the ACGIH chose a ceiling value because the literature indicated that short term exposures at or below 100 ppb resulted in symptoms of nose, throat, skin and eye irritation among medical workers using GA.

The Occupational Health and Safety Administration (OSHA) has not established a Permissible Exposure Limit (PEL) for GA. GA was not among the chemicals included when the PELs were established by OSHA in 1971. An attempt was made by OSHA in 1989 to update all of the existing PELs and to establish new PELs for additional chemicals such as GA, however, these PELs were rescinded in 1992 following a ruling by the U.S. Court of Appeals. In 1996, GA was included in an OSHA proposal to update the PELs (FR Notice of January 24, 1996, Vol. 61, page 1947) and in 1997 the OSHA laboratory published an updated version of the GA analytical method #64.

4.3 FQPA Considerations

From the available data on reproductive and developmental toxicity of GA, there was no evidence to suggest that offspring are more sensitive to the toxic effects of GA than parental animals. In addition, there was no evidence to suggest a neurotoxic effect of GA from the available toxicology data on this chemical. Based on this assessment, the Antimicrobial Division Toxicity Endpoint Selection Committee concluded that the special hazard-based FQPA factor can be reduced to 1x for risk assessments involving the FQPA safety factor.

5.0 RESIDENTIAL EXPOSURE ASSESSMENT

All of the glutaraldehdye (GA) products appear to be intended for use only in industrial or medical areas. There is one product (55195-3) containing GA that has labeling which could be interpreted to mean that it could be used in residential areas, however, it appears to be primarily intended for use in medical areas and it is assumed that this label will be amended to exclude use in residential areas. This product is a RTU surface spray which can be applied to hard surfaces such as counter tops, table surfaces and office furniture in medical clinics. In addition, the residential population may be exposed to household items such as laundry detergents and paints that have been treated with GA as a material preservative and emissions from cooling towers that have been treated with GA as a slimicide. Table 8 identifies the residential exposure scenarios assessed for GA.

Table 8 – Glutaraldehyde Residential Exposure Scenarios

Use	Exposure Scenario	Exposure Duration	Exposure Pathway	Application Rate (ppm)
Material Preservation of Laundry Detergent	Handler Exposure While Using Treated Laundry Detergent	Short Term	Dermal and Inhalation	100 to 1000
Material Preservation of Latex Paint	Handler Exposure While Using Treated Paint	Short Term	Dermal and Inhalation	100 to 1000
	Post Application Exposure to Treated Paint	Short Term	Inhalation	
Cooling Towers	Post Application Exposure to Cooling Tower Emissions	Long Term	Inhalation	20 to 100

5.1 Residential Handler Exposures and Scenarios Assessed

The residential handler exposure scenarios described in Table 8 were assessed to determine dermal and inhalation exposures. Because GA has a relatively high vapor pressure (0.1 mm Hg at 50% solution concentration), the unit exposure data from PHED and CMA are not applicable because these data are generally based upon chemicals that have a much lower vapor pressure (less than 1.0×10^{-4} mm Hg). When the vapor pressure is less than 1.0×10^{-4}, chemicals are airborne primarily as aerosols, while at a higher vapor pressure, chemicals are airborne primarily as vapors. In addition, the toxicology endpoints were derived from inhalation studies where the test animals were exposed to GA vapor. The painter inhalation exposures to the GA vapors were assessed using the EPA's Wall Paint Exposure Model (WPEM) and laundry detergent inhalation exposures were assessed using the EPA's Consumer Exposure Module (CEM). The dermal exposures were assessed by comparing the concentration in the paints and the laundry detergents with the concentrations used in the dermal toxicity studies.

4.1.1 Residential Painter Inhalation Exposure Assessment

In this section, the painter inhalation exposure to chemical vapor from the paint is assessed. HED utilized EPA's Wall Paint Exposure Model (WPEM) version 3.2 to estimate air concentrations resulting from the use of paint preserved with glutaraldehyde. WPEM was developed under a contract by Geomet Technologies for EPA OPPT to provide estimates of potential air concentrations and consumer/worker exposures to chemicals emitted from wall paint which is applied using a roller or a brush. WPEM uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. The emission data can then be combined with detailed use, workload and occupancy data (e.g., amount of time spent in the painted room, etc,) to estimate exposure. Specific input parameters include: the type of paint (latex or alkyd) being assessed, density of the paint (default values available), and the chemical weight fraction, molecular weight, and vapor pressure. Detailed information and the executable model can be downloaded from http://www.epa.gov/opptintr/exposure/docs/wpem.htm.

For this exposure assessment, the WPEM default scenario for the homeowner painter (RESDIY) was used. This WPEM default scenario assumes that the homeowner is exposed to the chemical in paint when painting the bedroom of a house (Zone 1) and in adjacent rooms (Zone 2) after painting. This default scenario includes 3 hours of painting in Zone 1, 15 hours in Zone 2 and 6 hours outside of the house. The following chemical specific inputs and WPEM default assumptions were used in the model:

- The molecular weight of GA is 100.1 amu and the vapor pressure is 0.10 mm Hg.
- The weight fractions of Glutaraldehyde in paint are 0.0001 or 0.001 based upon the application rates of 100 or 1000 ppm.

WPEM Default Assumptions from the RESDIY Scenario

- The air exchange rate is 0.45 air changes per hour which is the median value from the Exposure Factors Handbook (US EPA, 1997).
- The painting is done in a house that has an internal volume of 15,583 ft^3 which is the mean value from the Exposure Factors Handbook (US EPA, 1997).
- The walls of one bedroom are painted and the painted surface area is 452 ft^2.
- One coat of paint which has a coverage of 400ft^2/gallon is applied.
- The paint is latex flat with a density of 4600 grams/gallon.
- The adult occupant is in the house being painted, but not in the painted area.
- The duration of painting is 3.42 hours and 1.13 gallons of paint are applied.

The WPEM model was set to run at one minute intervals for 1 day. To yield an average daily concentration (ADC) that includes only the day of painting (for comparison to the short term RfC) the exposure frequency was set to 365 exposure events per year. The model results are summarized in Table 9 and the detailed model run is included in Appendix B. The results were converted from mg/m^3 to ppb using a conversion factor of 0.00409 mg/m^3 per ppb. Since a homeowner or do-it-yourself painter typically paints on an intermittent basis (i.e., once or twice a year), only short term exposures were assessed. At the maximum application rate, the 24 hour average air concentration of 22 ppb exceeds the RfC of 0.12 ppb by a factor of 180 and the inhalation exposures are of concern. At the minimum application

rate, the 24 hour air concentration of 2.2 ppb exceeds the RfC of 0.12 ppb by a factor of 18 and is also of concern.

Table 9 - Short-Term Inhalation Risk Summary for Residential Painters				
Application Rate	Painted Surface Area[A]	Air Exchange Rate per hour	C24-hour[B]	Short Term RfC
1000 ppm	452 ft^2	0.45	**22 ppb**	0.12 ppb
100 ppm			**2.2 ppb**	
A. Assuming the walls of one room are painted as specified in the RESDIY scenario of WPEM. B. The 24 hour average air concentration experienced by the residential painter on the day of painting. **Air concentrations in bold font indicate risks of concern because they ex ceed the RfC.**				

5.1.2 Residential Laundry Detergent Handler Inhalation Exposure Assessment

In this section, the laundry detergent handler inhalation exposure to GA vapor from laundry detergent is assessed. HED utilized EPA's Consumer Exposure Module (CEM) to estimate air concentrations resulting from the use of laundry detergent preserved with GA. Detailed information and the executable model can be downloaded from http://www.epa.gov/opptintr/exposure

For this exposure assessment, the CEM default scenario for the laundry detergent was used. This scenario assumes that the homeowner is exposed to the chemical in laundry detergent when using the laundry detergent in the utility room of a house. The following chemical specific inputs were used in the model:

- The molecular weight of GA is 100.1 amu and vapor pressure is 0.10 mm Hg.
- The weight fractions of Glutaraldehyde are 0.0001 or 0.001 based upon the application rates of 100 or 1000 ppm.

Since a resident does laundry on an intermittent basis (i.e., a few times per week), only short term exposures were assessed. The results of the CEM model run are included in Table 10 and the model run details are included in Appendix B. The 24 hour average air concentrations exceed the short term RfC at both application rates and are of concern.

Table 10 - Short-Term Inhalation Risk Summary for Laundry Detergent Handlers				
Application Rate	Amount of Laundry Detergent Used Per Day/ Duration of Use	Air Exchange Rate per hour	C24-hour[A]	Short Term RfC
1000 ppm	400 grams/0.667 hours	0.45	**2.6 ppb**	0.12 ppb
100 ppm			**0.26 ppb**	
A. The 24 hour average air concentration experienced by the laundry detergent handler on the day of detergent use. ***Air concentrations in bold font indicate risks of concern because the y exceed the RfC.**				

5.1.3 Residential Handler Dermal Exposure Assessment

The residential handler dermal exposures were assessed by comparing the concentrations in the paints and the laundry detergents with the concentrations used in the dermal toxicity studies. This methodology is based upon the fact that the film thickness of 40 ul/cm^2 that was applied in the dermal toxicity study is greater than the film thickness of 10 ul/cm^2 that occurs when a human dips a hand into water. This comparison is shown in Table 11 below and indicates that the dermal exposures are of concern at the high application rate of 1000 ppm (0.1 percent) because the Margin of Exposure (MOE) of 25 is less than the target MOE of 100. The dermal exposures are not of concern when the application rate is 250 ppm (0.025 percent) or less because the MOE is equal to or greater than 100.

Table 11 - Residential Handler Dermal Exposures

Application Rate (ppm)	Application Rate (Percent)	Glutaraldehyde NOAEL	NOAEL Concentration[A]	MOE[B] (Target MOE = 100)
1000	0.1	50 mg/kg/day	2.5%	25
250	0.025			100
100	0.01			250

A. The concentration of glutaraldehyde in the test solution applied at the NOAEL dose.
B. MOE = NOAEL Concentration (percent) / Application Rate (percent)

5.2 Residential Post-application Exposures

Representative postapplication scenarios assessed include inhalation exposures from treated paints and cooling tower emissions. Typically, paints used in a residential setting result in short term exposure durations (1 to 30 days) while ambient cooling tower emissions can result in long term exposures. Dermal exposures from clothing laundered in GA treated laundry detergent were not assessed because GA is highly soluble in water and would be washed away during the rinse cycle.

5.2.1 Residential Painting Post Application Exposure Assessment

The Wall Paint Exposure Model (WPEM) was used to estimate air concentrations resulting from the use of paint preserved with GA. The default assumptions from the WPEM RESADULT scenario were used. This scenario assumes that the home occupants are exposed to the chemical in paint in adjacent rooms (Zone 2) during painting and in the painted room (Zone 1) after painting. This scenario includes 7 hours in Zone 2, 8 hours in Zone 1 and 6 hours outside of the house. The following chemical specific inputs and default assumptions were used in the model:

Chemical specific inputs

- The molecular weight of GA is 100.1 amu and the vapor pressure is 0.10 mm Hg.
- The weight fractions of Glutaraldehyde in paint are 0.0001 or 0.001 based upon the application rates of 100 or 1000 ppm.

WPEM Default Assumptions from the RESADULT Scenario

- The air exchange rate is 0.45 air changes per hour which is the median value from the Exposure Factors Handbook (US EPA, 1997).

- The painting is done in a house that has an internal volume of 15,583 ft^3 which is the mean value from the Exposure Factors Handbook (US EPA, 1997).
- The walls of one bedroom are painted and the painted surface area is 452 ft^2 based upon the assumption that ten percent of the house is painted per year.
- One coat of primer which has a coverage of 200 ft^2/gallon and one coat of paint which has a coverage of 400ft^2/gallon are applied.
- The paint is latex flat with a density of 4600 grams/gallon.
- The adult occupant is in the house being painted, but not in the painted area.
- The duration of painting is 3.99 hours during which 2.26 gallons of primer and 1.13 gallons of paint are applied.

The WPEM model was set to run at one minute intervals for 1 day. To yield an average daily concentration (ADC) that includes only the day of painting (for comparison to the short term RFC) the exposure event frequency was set to 27,375 exposure events per lifetime. The air concentrations are given in Table 12 and indicate that risks are of concern at both the maximum and minimum application rates because the 24 hour average air concentrations exceed the short term RFC.

Table 12- Post Application Risk Summary for Glutaraldehyde Treated Paint

Application Rate	Area Painted	Air Exchange Rate	C24 in Zone 1 (ppb)	C24 in Zone 2 (ppb)	C24 at person[A] (ppb)	Short Term RfC (ppb)
1000 ppm	452 ft² (one room)	0.45 ACH	98	33	**37**	0.12
100 ppm			9.8	3.3	**3.7**	

A. Average air concentration experienced by the resident person for the first 24 hours during and after painting.

Air concentrations in bold font indicate risks of concern because they exceed the RfC.

5.2.2 Cooling Tower Emissions Exposure Assessment

Cooling towers serve as heat exchangers in many industrial and commercial processes that need to dissipate heat to the atmosphere. Because some cooling towers service apartment and office buildings, there is a potential for residential exposure to cooling tower emissions of GA. As discussed in MRIDs 466822-04 (McCready 2003) and 466822-06 (McCready 2002), these potential emissions were evaluated using a model (CT-EVAP) which was validated with air sampling at a representative cooling tower that was treated with 100 ppm GA. Two cooling towers were evaluated at Buildings 96 and 203 of the Bound Brook, New Jersey Dow Chemical Facility and one cooling tower was evaluated at a hospital in California. Air samples were taken at the Building 203 cooling tower for comparison to the model predictions. One sample was taken 30 cm downwind of the eliminator slats and several samples taken at other locations. The results of the modeling and air sampling are listed in Table 13; however, these results are inconclusive because of the small number and short duration of the samples.

Table 13 - Air Concentrations from Glutaraldeyde Cooling Tower Emissions

Cooling Tower	Application Rate[A]	Water Capacity (Gallons)	Drift Rate	Maximum Predicted Concentration (ppb)	Maximum Measured 15 Minute Air Concentration[B] (ppb)	Average Predicted Air Concentration (ppb)
Building 96	63 ppm	14,400	0.005%	3.4 @ 1 hour	N/A	**1.3[C]**
Building 203	100 ppm	9,000	0.005%	7.1 @ 10 min	4.9	**2.2[C]**
California Hospital	60 ppm	2,000	0.005%	4.9	N/A	**0.049[D]**

A. The label application rate is 20 to 100 ppm as listed in Table 2.
B. This sample was collected 30 cm downwind of the eliminator slots. Several other samples were also collected and were below the LOD of 4.9 ppb.
C. Predicted average over one day (1440 minutes).
D. Predicted averaged over one week (10080 minutes).

Air concentrations in bold font indicate risks of concern because they exceed the RfC of 0.005 ppb.

5.3 Residential Exposure Data Limitations/Uncertainties

There are several data limitations and uncertainties associated with the residential handler and postapplication exposure assessments which include the following:

- It is not known what percentage of paints and laundry detergent used in residential areas are treated with glutaraldehyde.
- The vapor pressure of pure glutaraldehyde is unknown because glutaraldehyde is unstable in the pure form, therefore, the vapor pressure for a 50% solution of GA was used in the WPEM and CEM modeling runs.
- It was assumed that the treated products contain 100% liquids and no adjustments were made for solids content. Although it is understood that paints contain approximately 50% liquids, the assumption of 100% liquids does not result in an over-estimate of exposure because the vapor pressure of 0.1 mm Hg, which was used to represent 100% GA, is actually the vapor pressure for 50% GA.
- The Wall Paint Exposure Model is designed to estimate indoor-air concentrations and associated inhalation exposures for interior applications involving alkyd or latex primer/paint. The chamber tests on which the emission algorithms are based involve a limited set of chemicals with a correspondingly limited range of properties (molecular weight and vapor pressure). Actual monitoring data could be used to refine the exposures and risks estimated in this assessment.
- The cooling tower emissions model has been validated with only a limited set of air concentration data that were collected over a short time period. Additional data collected for longer periods of time could be used to refine the risks to some extent, however, it is unlikely that GA concentrations at the long term RFC of 0.005 ppb could be detected using current methodology. The OSHA Analytical Method for glutaraldehyde has a limit of detection 0.027 ppb for a four hour sample collected at 2 liters per minute when the ozone level is less than 10 ppb. Ozone levels in excess of 10 ppb cause negative interference and require reduced sampling times or use of an ozone scavenging filter.

6.0 OCCUPATIONAL EXPOSURE ASSESSMENT

6.1 Occupational Handler Exposures

Occupational Handler Scenarios

The term "handler" applies to individuals who mix, load, and apply pesticide products. There are several occupational handler exposure scenarios that involve glutaraldehyde (GA) products. These scenarios are listed below:

Open pour GA products into industrial processes
Automatic addition of GA products into industrial processes
Mop Animal and Poultry Housing with solutions of GA products
Spray or fog Animal and Poultry Housing with solutions of GA products
Apply RTU spray to non-critical hard surfaces in medical areas
Apply RTU wipes to non-critical hard surfaces in medical areas.
Connect medical waste collection devices that contain GA.

Occupational Handler Exposure Assessment Rationale

GA dermal irritation exposures and risks were not estimated for occupational handler exposures. Instead, dermal irritation exposures and risks will be mitigated using default personal protective equipment requirements based on the toxicity of the end-use product. To minimize dermal exposures, the minimum PPE required for mixers, loaders, and others exposed to end-use products containing concentrations of AD that result in classification of category I, II, or III for skin irritation potential will be long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron. Once diluted, if the concentration of GA in the diluted solution would result in classification of toxicity category IV for skin irritation potential, then the chemical-resistant gloves and chemical-resistant apron can be eliminated for applicators and others exposed to the dilute. Note that chemical-resistant eyewear will be required if the end-use product is classified as category I or II for eye irritation potential.

Because GA has a relatively high vapor pressure (0.1 mm Hg at 50% solution concentration), the unit exposure data from PHED and CMA are not applicable because these data are generally based upon chemicals that have a much lower vapor pressure (less than 1.0×10^{-4} mm Hg). When the vapor pressure is less than 1.0×10^{-4}, chemicals are airborne primarily as aerosols, while at a higher vapor pressure, chemicals are airborne primarily as vapors. There are 5 GA replicates in the CMA dataset, however, and they are summarized in Table 14. The CMA data is of limited usefulness because the limit of detections were very high due to the short sampling times and limitations of the adsorbent tube method that was used. However, based on these data, the air concentrations for occupational handlers exceed the RfC and are of concern.

Table 14 – Summary of GA Air Concentration Data from the CMA Study					
Rep	Use	Operation Monitored	Amount Handled During Monitoring	Sample Duration (minutes)	GA Air Concentation (ppb)
54	Cooling Tower	Liquid Pour from 55 gallon drum	504 lbs of a 45% product	5	<660
53	Metal Working Fluid	Liquid Pour from a 55 gallon drum	133 lbs of a 45% product	22	<290
82	Metal Working Fluid	Liquid Pump from a 55 gallon drum	92 lbs of a 45% product	16	<71
91	Disinfect dental instruments	Liquid Pour from a 1 gallon container into disinfection tray	1.8 lbs of 2.0% product	6	<160
98	Disinfect dental instruments	Same as above	4.4 lbs of 2% product	5	540
All of the measured air concentrations exceed the TLV of 50 ppb and the RfC of 0.32 ppb.					

Use of Other Exposure Data to Estimate Glutaraldehyde Risks

Other air sampling data were reviewed to determine if measured GA exposures typically exceed the RfCs. The following data sources were reviewed:

*Open Literature studies cited in the ACGIH Documentation of the Glutaraldehyde TLV

*Open literature and proprietary studies cited by Dow Chemical in MRID 466822-01 "Summary of Worker Inhalation and Exposure Data to Glutaraldehyde-Containing Biocidal Products"

Most of the above data were collected to compare GA exposure to the TLV which is a ceiling value and it is not comparable to the short term RfC of 0.32 ppb which is based upon an eight hour average exposure. When assessing ceiling values, air samples of 15 minutes or less in duration are collected at peak exposure periods during the workday. Because only peak exposures are of interest when comparing exposures to ceiling exposure limits, the intervals between peak exposures are usually not evaluated. By contrast, sampling that is conducted to evaluate 8 hour exposure limits usually includes all parts of the workday.

Summary of Exposure Data Cited in the ACGIH TLV documentation.

Most of the exposure data cited in the ACGIH TLV documentation is from medical uses where instruments, such as endoscopes, were disinfected with GA. Although these uses are not included in the EPA labels, this exposure data is included as weight of evidence that significant exposures occur when handling GA in relatively small amounts. GA air concentrations ranged from <0.5 ppb to 570 ppb depending on the type of process, the ventilation conditions and other site specific factors. The highest result of 570 ppb was a peak measurement taken during the use of a 0.15% solution of GA and the corresponding 8 hour TWA was 100 ppb. GA air concentrations were greater during manual disinfection than during automated disinfection. A summary of these data is included in Table 15.

Table 15 –GA Air Concentrations During Endoscopy Disinfection

Study	Operation	Solution Strength	Sample Type	GA Air Concentration (ppb)	Comments
Binding and Witting, 1990	Disinfection in operating theatres	0.025%	Peak 8 hr TWA	30 10	
		0.15%	Peak 8 hr TWA	570 100	
Leinster, Baum and Baxter, 1993	Cold Sterilization in English Hospitals		STEL	<0.8 to 30 (n=39)	Note 1
Tkaczuk, Pisaniello and Crea, 1993	Manual Cold sterilization of endoscopes		STEL TWA (133 min)	77 to 105 (n=2) 43 (n=1)	
	Dental assistant, radiography, embalmer and egg collectors		STEL and TWA	<50	
Campbell and Beach, 1994	Cold sterilization of endoscopes	2%	STEL	160 and 230	Note 2
Burge, 1989 Norback, 1988	Manual Cold Sterilization		STEL	2.5 to 35	
	Automatic Sterilization		STEL	2.5 to 7.5	Good ventilation
	Automatic Sterilization		STEL	2.5 to 7.5	Poor ventilation
Jachuck et al, 1989	Cold sterilization of endoscopes	2%	TWA (60 min)	50 to 120	
Pisaniello, Gun, Tkaczuk, et al., 1997	Cold sterilization		STEL	>200 (n=4) <200 (n=58) 100 to 200 (n=10)	
NIOSH HETA 90-296	Cold Sterilization	2%	Various	ND to 80	

Note 1 - Sample times ranged from 4 to 26 minutes
Note 2 - Samples taken with and without overhead exhaust fan.
Some of the measured air concentrations exceed the TLV of 50 ppb and all exceed the RfC of 0.32 ppb.

Summary of Exposure Data Cited by Dow Chemical

Dow Chemical provided a summary of GA exposure data in MRID 466822-01. Samples have been collected during GA use in industrial processes such paper manufacture, aluminum rolling and oil drilling. Samples have also been collected during the manufacture and drumming (i.e. packaging) of GA products. Most of the data are in the form of 15 minute samples that were taken to compare exposures with the TLV, however, some of the drumming samples prior to 1989 were taken over a full shift. A summary of this data is given in Table 16 and a discussion of the data is included in section 6.1.1.

Table 16 – GA Air Concentrations Measured During Industrial Operations

Location	Operation	Solution Strength	Sample Type	Sampled Period (minutes)	GA Air Concentration (ppb)	Source
Latex Plant (CA)	Addition to truck sump	45%	PBZ	15	27	SIDS
Paper Mill (GA)	3 feet above wire at machine #3		Area		ND	SIDS
Paper Mill (Canada)	1 foot above machine chest opening at various addition rates		Area	15	ND - 220 (LOD=20)	UCC, 1998
Paper Mill (Kent UK)	Above blend and machine chests at various addition rates		Area	15	ND (n=5) (LOD=30)	UCC 1998
Paper Mill (Belgium)	Pumping biocides at various locations	50%	Area	60	4 - 130	SIDS
Paperboard Mill	Various Locations throughout process	50%	Area	30-60	ND - 1.8 (n=18)	SIDS
Drilling Field (BP Alaska)	Addition to drilling mud	Aldacide G			20 - 120 (n=9)	SIDS
Aluminum Mill	Hot Rolling - Air in metal working fluid sump	45%	Area	30	6 - 122	SIDS
Aluminum Rolling Plant Breakdown Mill	Mill floor during rolling	Uconex 345	Area	15	ND	SIDS
	Inside covered sump		Area	15	122 - 175 (n=2)	SIDS
	Adjacent to spray nozzles near operators		Area	15	6 - 8 (n=3)	SIDS
Aluminum Hot Rolling Mill (NE US)	Addition areas over tanks near rolling mill	Not Reported	Area	15	ND - 180[A] (n=23) (LOD = 46)	UCC, 1994
	Walking around in mill during operation		PBZ	15	<46 (n=2)	UCC, 1994
Paint Spray Booth, GM Truck Plant	Emissions at various locations around booth		Area	30	ND - 158 (LOD=1)	SIDS
Glute Mfg Plant/(WV)	Drumming (prior to 1989)	25-50	PBZ	Full Shift	10 - 170	Teta 1995
	Drumming (1989 to 1992)	25-50	PBZ	15	10 - 340 (n=88)	SIDS
Glute Formulation Plant (Australia)	Formulating and packaging at a well ventilated facility	25-50	PBZ	15	70 - 100	SIDS
UCC Glute Mfg Plant (WV)	Drumming (1990-1996)	25-50	PBZ	15	70 - 130	SIDS
	Filling totes (1994-1997)	25-50	PBZ	15	<10 - 120	SIDS
	Disconnecting hose from truck (1994-1997)	25-50	PBZ	15	<50	SIDS

Notes
PBZ - Personal breathing zone sample taken on the worker.
Area - Area sample
A. The highest result of 180 ppb was measured during addition over the tank with the door open.

6.1.1 Occupational Handler Exposure and Risk Assessment

Most of the available exposure data are from short term samples of approximately 15 minutes in duration and they were taken as a comparison to the ACGIH TLV of 50 ppb. Although many of the short term samples exceeded the RfC of 0.32 ppb, these samples are not comparable to the RfC because the un-sampled periods probably had lower exposures than the sampled period.

The drumming samples prior to 1989 were taken over a full shift and the results ranged from 10 to 170 ppb. All of these samples exceeded the short term RfC of 0.32 ppb.

6.1.2 Professional Painter Inhalation Exposure Assessment

In this section, the professional painter inhalation exposure to GA vapors during painting with GA treated paint was assessed using the WPEM Model. The WPEM default scenario (RESPROF) for the professional painter was used and this scenario assumes that two professional painters are exposed to a chemical in paint while painting an entire apartment in a work day. The following chemical-specific and WPEM default inputs were used:

Chemical Specific

- The molecular weight of GA is 100 amu and the vapor pressure is 0.10 mm Hg.
- The weight fractions of Glutaraldehyde in paint are 0.0001 or 0.001 based upon the application rates of 100 or 1000 ppm.

WPEM Default Assumptions from the RESPROF Scenario

- The air exchange rate is 0.45 air changes per hour which is the median value from the Exposure Factors Handbook (US EPA, 1997).
- The painting is done in an apartment that has an internal volume of 7,350 ft^3 which is the mean value from the Exposure Factors Handbook (US EPA, 1997).
- The surface area painted is 2131 ft^2.
- One coat of primer which has a coverage of 200 ft^2/gallon and one coat of paint which has a coverage of 400ft^2/gallon are applied.
- The paint is latex flat with a density of 4600 grams/gallon.
- The duration of painting is 9.4 hours based upon the labor production rate of 337.5 ft^2 per hour for painting with a roller at 400 ft^2/gallon.
- The amount of paint used is 10.66 gallons for the primer coat and 5.33 gallons for the finish coat.

The results of modeling runs are included in Appendix B and the risks are summarized in Table 17. Since professional painters can paint indoors on a year round basis only long term exposures were assessed. Because the C-8hour air concentrations exceed the long term RfC of 0.015 ppb, the inhalation exposures are of concern at both the maximum and minimum application rate. The C15-min air concentrations also exceed the TLV of 50 ppb.

Table 17 - Inhalation Risk Summary for Occupational Painters							
Application Rate	Painted Surface Area	Air Exchange Rate	Hours per Day	C15-min[A] (ppb)	ACGIH TLV (ppb)	C-8hour[B] (ppb)	Long Term RfC (ppb)
1000 ppm	2131 ft^2 (one apartment)	0.45 per hour	8	**680**	50	**540**	0.015
100 ppm				**68**		**54**	

A. Maximum 15 minute average air concentration.
B. Maximum 8 hour average air concentration on the day of painting.

Air concentrations in bold font are concern because they exceed the TLV and the RfC.

6.1.3 Medical Clinic Hard Surface Cleaning Inhalation Exposure Assessment

There are three products (15136-9, 55195-3 and 55194-5) which are used to clean non-critical hard surfaces in medical clinics, dental clinics and veterinary offices. Two of theses products are RTU sprays and one is an RTU wipe. In this section, worker inhalation exposure to GA vapors during hard surface cleaning with these products was assessed HED utilized EPA's Consumer Exposure Module (CEM) to estimate air concentrations resulting from the use of glutaraldehyde as a general purpose cleaner. Detailed information and the executable model can be downloaded from http://www.epa.gov/opptintr/exposure

The following chemical-specific inputs were used in the model:

- The molecular weight of GA is 100 and the vapor pressure is 0.10 mm Hg.
- The weight fraction of GA is 0.00275 (0.275%) as stated on the product labels.
- The mass of product used is 123 grams which is a default assumption in CEM.
- The minimum air exchange rate of 0.45 air changes per hour (ACH) is based upon the assumption that a clinic would be located in a residence.
- The maximum air exchange rate of 4 ACH based upon the assumption that a clinic would be located in a well ventilated hospital building.

The results of the CEM model runs are included in Appendix B and the risks are summarized in Table 18. It should be noted that CEM calculates daily exposures as 24 hour TWAs. The 24 TWAs were converted to 8 hour TWAs by assuming that all of the exposure occurs during the workday. This assumption is probably valid because the highest air concentrations occur during and immediately after use and then decline due to ventilation. Since medical surface cleaners can be used on a year round basis, only long term exposures were assessed. Because the 8 hour time weighted average (TWA) air concentrations exceed the long term RfC of 0.015 ppb, the inhalation exposures are of concern at both the low and high air exchange rates. The peak exposure is also of concern at the low air exchange rate because it exceeds the ACGIH TLV of 50 ppb.

Table 18 - Inhalation Risk Summary for Medical Hard Surface Cleaning								
Weight Fraction	Amount of Product Used	Duration of Use	Air Exchange Rate	Peak Concentration (ppb)	ACGIH TLV (ppb)	24 Hour TWA (ppb)	8 Hour TWA (ppb)	Long Term RfC (ppb)
0.00275	123 grams	1.42 hours	0.45	**130**	50	26	**78**	0.015
			4	21		0.033	**10**	
Air concentrations in bold font are of concern because they exceed the TLV and/or the RfC.								

6.2 Occupational Post-application Exposures

6.2.1 Fogging Exposure Assessment

GA is used for fogging poultry houses in preparation for a new flock of birds. Exposures to GA can occur after fogging when the workers re-enter the fogged area to finish cleanup. Only inhalation exposures were assessed, because dermal post application exposures are presumed to be negligible because the GA evaporates rapidly from the fog as predicted by the Aero-Evap model presented in MRID 466822-07 (McCready, 2004). The inhalation exposure assessment was conducted using the single chamber decay formula from the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2). This assessment was based upon the application parameters listed in the Virocide Label (EPA Reg #71355-1) because this label has the most explicit instructions for fogging application. The following assumptions were made:

- The area being fogged is a one-chamber barn with dimensions of 300 ft x50 ft x10 ft (AD standard assumption).
- The air exchange rate is 4 air changes per hour. (Jacobson, 2005).
- Fogging occurs instantaneously, so that the entire mass of product is mixed homogeneously with the indoor air as soon as fogging commences.
- The concentration of the fogging solution is 2.1 percent GA. This is based upon the dilution rate of 1 part product per 4 parts water times from label #71355-1 which contains 10.725% GA.
- The application rate of fogging solution is 125 ounces per 1000 cubic yards (yd^3) based upon label #71355-1.
- The application rate in terms of ai is 0.17 lb ai per 1000 yd^3 based upon the following: (125 oz applied per 1000 yd^3 / 128 oz per gallon) x (8.35 lb per gallon * 2.1% ai)
- The initial concentration is 101 mg/m^3 (25,000 ppb) based upon the following: (0.17 lb ai * 454,000 mg per lb) / (1000 yd^3 * 0.764 m^3 per yd^3)

The calculations are included in Spreadsheet A and a summary of the results is included in Table 19. The air concentrations decline to less than the TLV in 94 minutes and to less than the RfC in 170 minutes.

Table 19 - Glutaraldehyde Air Concentrations After Fogging a Poultry House

Elapsed Time (minutes)	Air Concentration (ppb)	Relevant Standard (ppb)
0	25,000	50 - ACGIH TLV
94	47	50 - ACGIH TLV of 50
170	0.030	0.032 - EPA Short Term RfC

Exposure data for spraying and fogging applications was also included in the Dow Chemical Exposure Data Summary (MRID 466822-01) and are summarized in Table 20 below.

Table 20 – GA Air Concentrations Measured During Spraying and Fogging Applications

Location	Operation	Solution Strength	Sample Type	Sampled Period (minutes)	Results (ppb)	Source
Poultry Hatchery	Machine washing hatching trays and chick boxes	1000 ppm	Area	10-60	ND-68 (n=3)	UCC 2000
	Spraying egg carts		Area	10-60	14	UCC 2000
	Atomizing hatcher and chick room		Area	10-60	150 – 1760[A] (n=4)	UCC 2000
Turkey Hatchery	Turkey housing treated with UCARSAN 4256	1000 ppm	PBZ	15	26 initial ND at 15 min 31 at 35 min	UCC 2000
Chicken Hatchery	Fogging: 0 to 135 minutes after application	500 ppm	Area	10 – 20	530 initial 20 at 135 min	UCC 2000
Chicken House – Broiler Production	Spraying – manual	2%	PBZ Area	15	120 (n=1) 30 to 80 (n=3)	SIDS
	Spraying - Automatic	2%	Area	15	20 to 50 (n=3)	SIDS
Chicken House – Broiler Production	Fogging	600 ppm	Area	15	20 to 50	UCC 2000
Church in Taiwan	Hot Fogging for SARS Disinfection Trial	3%	Area	15	>5000[B] at 30 min >5000[B] at 60 min 3000 at 120 min 140 at 240 min	Trawick

A. Fog contacted sampling tube. Next highest result was 1060 ppb
B. Break-through occurred. The calculated initial air concentration was 48,000 ppb based upon the application rate.

6.2.2 Metal Working Fluids (MWF) Exposure Assessment

Dermal Exposure

There is a potential for dermal exposure when a machinist handles treated metalworking fluids. This exposure occurs after the glutaraldehyde has been added to the MWF which is used by a machinist. The dermal exposures were assessed by comparing the concentrations in the treated MWF with the concentrations used in the dermal toxicity studies. This comparison is shown in Table 21 below and indicates that the dermal exposures are of concern at the high application rate of 270 ppm (0.027 percent) because the MOE of 92 is less than the target MOE of 100. The dermal exposures are not of concern at the low application rate of 36 ppm (0.0036 percent) because the MOE exceeds 100.

Table 21 - Dermal Risks from MWF Treated with Glutaraldehyde

Application Rate (ppm)	Application Rate (Percent)	Glutaraldehyde NOAEL	NOAEL Concentration[A]	MOE[B] (Target MOE = 100)
270	0.027	50 mg/kg/day	2.5%	92
36	0.0036			690

A. The concentration of glutaraldehyde in the test solution applied at the NOAEL dose.
B. MOE = NOAEL Concentration (percent) / Application Rate (percent)

Inhalation Exposure

Inhalation exposures are also of concern for machinists working with treated MWF, but at this time insufficient data are available to assess the exposure. Inhalation exposure to MWF additives is normally assessed at EPA by assuming that MWF aerosol exposure would not exceed the OSHA PEL of 15 mg/m^3 and that the chemical additive would also be present as an aerosol in proportion to the amount added. The estimated air concentration is then the product of the weight fraction of the chemical added to the MWF times the OSHA-PEL. GA has a much higher vapor pressure than most MWF additives and would also become airborne as a vapor, therefore, the OSHA PEL oil mist approach is not valid.

6.5 Data Limitations/Uncertainties

There are several data limitations and uncertainties associated with the occupational handler and postapplication exposure assessments. These include:

- Most of the air sampling data was collected to compare GA exposure to the TLV of 50 ppb which is a ceiling value and it is not comparable to the RfC of 0.32 ppb which is based upon an eight hour time weighted average (TWA) exposure. When assessing ceiling values, short term samples of 15 minutes or less in duration are collected at peak exposure periods during the workday. Because only peak exposures are of interest when comparing exposures to ceiling exposure limits, the intervals between peak exposures are usually not evaluated. By contrast, sampling that is conducted to evaluate 8 hour TWA exposure limits usually includes all parts of the workday.
- Most of the samples were collected prior to 1996 and in 1997 the OSHA sampling method was updated to allow for longer sampling times with lower detection limits.

The updated method allows for samples up to 4 hours in duration to be collected with a limit of detection of 0.027 ppb which is less than the short term RFC of 0.32 ppb. This method is affected by ozone interference; however, when the ozone concentration exceeds 10 ppb and reduced sampling times may be required.

- Some of the data submitted by Dow Chemical includes 8 hour TWA samples taken at during drumming at the production plant, however, it is not known if the conditions at the plant are representative of conditions at end user facilities. Although larger quantities are handled at the plant which might increase exposure, engineering controls such as closed system loading and local exhaust ventilation are also probably present at the plant which would reduce exposure.
- It is not known what percentage of paints used by professional painters in the residential environment are treated with GA.
- It was assumed that the treated products contain 100% liquids and no adjustments were made for solids content. Although it is understood that paints contain approximately 50% liquids, the assumption of 100% liquids does not result in an overestimate of exposure because the vapor pressure of 0.1 mm Hg which was used to represent 100% glutaraldehyde is actually the vapor pressure for 50% glutaraldehyde.

7.0 Recommendations to Mitigate Glutaraldehyde Risks of Concern

Residential Risks of Concern

To mitigate the residential risks arising from the use of glutaraldehyde treated paint or laundry detergent it is recommended that the treatment rates be reduced.

Occupational Risks of Concern

Glutaraldehyde should be only be used with appropriate work practices and engineering controls such that peak exposures do not exceed the ACGIH TLV and average daily exposures do not exceed the relevant RfCs. This can be accomplished by one or more of the following:

- The open pouring of glutaraldehyde solutions should be minimized to low volume applications where the amount of concentrate handled is less than a couple of gallons per day.
- Automatic addition systems that minimize operator exposure to the concentrated product should be used when handling larger amounts of glutaraldehyde. If this is not feasible then local exhaust ventilation should be used to reduce glutaraldehyde exposure.
- Fogging of poultry houses should only be done in such a way that the operator is outside the poultry house when applying the fog.
- Glutaraldehyde treated paint should only be used in well ventilated areas.
- Glutaraldehyde hard surface cleaning products should only be used in small amounts in areas with very good general ventilation.

8.0 REFERENCES

Dang, 1997. The Use of Models for Estimating Exposure and Risk of Antimicrobials in Metalworking Fluids. AAMA MWF Symposium, September 15-19, 1998.

Dow, 2005. Glutaraldehyde Smart Meeting, Dow Chemical Company, September 21, 2005

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

McCready, 2002. Potential Glutaraldehyde Air Emissions from a Cooling Tower and Exposure, David McCready, PhD, 2002, Sponsored by Dow Chemical, (MRID 466822-06)

McCready, 2003. Estimating Air Emissions of a Biocide from a Cooling Tower, David McCready, PhD, 2003, Sponsored by Dow Chemical, (MRID 466822-04)

McCready, 2004. Volatilization of Indoor Generated Aerosols, David McCready, PhD, 2004, Sponsored by Dow Chemical, (MRID 466822-07).

NICNAS, 1994, National Industrial Chemicals Notification and Assessment Scheme - Priority Existing Chemical No. 3 - Glutaraldehyde Full Public Report, Commonwealth of Australia, July 1994

NIOSH, 1983. National Occupational Exposure Survey.

SIDS, 1996. Initial Assessment Report on the HPV Phase 4 Chemical, 1996.

Teta, 1995. "Absences of Sensitizations and Cancer Increases Among Glutaraldehyde Workers", Teta, MJ, Avashia E, Cawley T and Yamin A., Toxic Substances Mechanisms; 14: 293-305. 1995.

Trawick, 2003. Assessment of Glutaraldehyde Air Concentrations during a Trial Fogging Application in Taiwan, Earl Trawick 2003, Sponsored by Dow Chemical (MRID 466822-02)

UCC, 1994. Union Carbide Report on Glutaraldehyde in Aluminum Hot Rolling Mills (MRID 441812-01)

UCC, 1998. Union Carbide Report on Vapor Concentrations of Piror 850 in Paper Mills, 1998 (No MRID)

UCC, 2000. UCARCIDE 250 Antimicrobial: Glutaraldehyde Vapor Studies in Animal Housing Sanitizer (MRID 453695-01) Union Carbide, November 14, 2000

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

USDA, 2002, Crop Profile for Poultry in Florida

US EPA, 1997. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. EPA Office of Pesticide Programs-Human Health Effects Division (HED). Dated December 18, 1997.

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

US EPA, 1998. PHED Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1. Washington, DC: U.S. Environmental Protection Agency.

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, 2001. HED Science Advisory Council for Exposure. Policy Update, November 12. Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessment, February 22, 2001.

US EPA, 2006a. Incident Reports Associated with Glutaraldehyde. Jonathen Chen Ph.D., February 9, 2006.

US EPA, 2006b. Glutaraldehyde - Report of the Antimicrobials Division Toxicity Endpoint Selection Committee (ADTC), February 9, 2006 .

US EPA, 2006c. Use Closure Memo for Glutaraldehyde

Vermont, 2003. The Vermont Agency of Agricultural Food and Markets

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Egg Sanitation	Ready to Use 464-702 464-700	Spray	0.3 fl oz per 1 gallon of water	None Stated
	Soluble Concentrate 464-689 464-715 464-716	Spray	1.0 fl oz. Per 1 gallon of water	None Stated
Farm Equipment and Animal Housing Buildings	Ready to Use Solution 464-702 464-700	Spray	Not Stated	Remove all animals and feed from the premises. Remove all portable equipment and empty all feeders and water troughs. If not removed, all treated feeders and waterers must be thoroughly rinsed with potable water prior to reuse. Remove all litter and manure from floors and other surfaces. If litter is not removed, allow to stand after treatment for at least ten minutes before repopulation. Allow to stand for at least five minutes or until dried.
	Soluble Concentrate 464-696 464-689 71355-1 464-715 464-716 66171-7			
	Soluble Concentrate 71355-1	Fogging	None Stated	The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1 to 4 hours after the actual fogging. If the room or building must be entered, then the individuals entering must wear a self contained respirator approved b NIOSH/MSHA, goggles, long shirt, sleeves and pants.
Hatcheries, Setters, and Chick Processing Facilities	Ready to Use Solution 464-702 464-700	Spray	20 to 100ppm active	Remove all animals from the area. Clean out feathers, fluff, or other debris,
	Soluble Concentrate 464-696 464-689 464-715			

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	464-716 71355-1			
Trays, Racks, Carts, Chick Boxes, Cages, and Other Hard Surfaces	Ready to Use Solution 464-702 464-700	Immersion	None Stated	None stated
		Spray	None Stated	None Stated
	Soluble Concentrate 464-696 464-689 464-715 464-716	Spray	None Stated	None Stated
	Soluble Concentrate 464-696 464-689 464-715 464-716 71355-1 66171-7	Spray	None Stated	Remove all filth and heavy debris from surfaces.
	Ready to Use Solution 464-700	Spray	None Stated	None Stated
Commercial, institutional and industrial premises and equipment				
Veterinary Facilities, Janitorial, Commercial and Industrial Facilities, Hard Surfaces	Impregnated Materials 55195-4	Wipes	None Stated	None Stated
Medical Waste (laboratories, biomedical research facilities, nursing homes, human and animal waste)	Ready to Use Solution 71814-1	None Stated	None Stated	None Stated
	Microencapsulated 46781-10			
Urinals	Ready-to-use Solution 55195-3	Spray	None stated	None stated

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Cages	Ready-to-use Solution 55195-3 15136-9	Spray	None stated	None stated
Veterinary Hospitals	Soluble Concentrate 71355-1	Spray	None Stated	None Stated
Residential and public access premises				
Hard Surfaces	Ready-to-use Solution 55195-3 15136-9	Spray	None stated	None stated
Medical premises and equipment				
Liquid Medical Waste	Water Soluble Package 72675-1	None Stated	None Stated	None Stated
Hospitals, Medical offices, Dental Offices,	Impregnated Materials 55195-4	Wipes	None Stated	None Stated
Medical Waste	Ready to Use Solution 71814-1 Microencapsulated 46781-10	None Stated	None Stated	None Stated
Exam Tables	Ready-to-use Solution 55195-3	Spray	None Stated	None stated
Dialysis Machine	Ready to Use Solution 8383-6	None Stated	None Stated	None Stated
Hospital Surfaces	Soluble Concentrate 71355-1	Spray	None Stated	None Stated
Materials preservatives				
Industrial, institutional and consumer in-can process and products	Soluble concentrate 464-692 464-688 464-706 464-705 464-703 464-718 464-693	None Stated	Use 0.2 – 4.4 lbs of product per 1000 lbs. of water content	At no time should the level of the antimicrobial exceed 2.2% Non food contact applications

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	464-704 464-688 464-703 464-706 464-705			
	Soluble concentrate 68868-2 1677-206 1667-205 33753-26 33753-27 33753-31	None Stated	Use 2.8 – 93.3 fl. Oz. of product per 100 gallons of water content	At no time should the level of the antimicrobial exceed 2.2% Non food contact applications
Concrete admixtures	Soluble concentrate 464-692 464-688 464-706 464-705 464-718 464-706 464-705	None Stated	Add 2.0 16 lbs per 1000 lbs. of admixture	None stated
	Soluble concentrate (EPA Reg No. 68868-2	None Stated	Use 2.8 – 26 fl. Oz. of product per 100 gallons of water content	At no time should the level of the antimicrobial exceed 2.2%
Reverse osmosis membranes	Soluble concentrate 464-692 464-688 464-706 464-705 464-718 1677-206 33753-26 33753-27 33753-31 464-688 464-706	Immerse elements in tank	Immerse reverse osmosis elements in a 0.2% - 4.0% concentration of antimicrobial Add a 0.2% - 4.0% concentration of antimicrobial to the tank in the circulation system (for installed out of service equipment)	Not for sale and use in California

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	464-705			
Industrial processes and water systems				
Oils Storage tanks	Soluble concentrate 1007-42	Inject where good mixing can be assured.	20 to 500 ppm	For use with closed delivery systems only
Water Floods Water Floods (cont.)	Soluable Concentrate 464-692 464-701 464-702 464-714 464-718 1448-354 1448-421 1448-422 1448-423 67869-36 59894-7 1677-206 1677-205 59894-4 10707-40 10707-41 33753-30 33753-27 33753-31	Add to water flood system at point of uniform mixing	Initial Treatment: Add 110 to 8,333 ppm per 1,000 gallons flood water. Repeat until control is achieved. Subsequent Dose: add 22 to 5,500 ppm per 1,000 gallons of flood water to the system weekly or as needed.	Do not use in any marine and or estuarine oil field applications.
	Soluble concentrate 464-700 464-709	Add to water flood system at point of uniform mixing	add 300 to 16,670 ppm per 1,000 gallons of flood water to the system weekly or as needed.	
	Soluble concentrate 8133-20 464-688 464-694 33753-26		Initial Treatment: 200 to 10,000 ppm per 1,000 gallons flood water Subsequent Dose: 40 to 10,000 ppm to the system weekly	

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Drilling Muds	Soluble concentrate 59894-4 1448-354 1448-421 1448-422 1448-423	Added to a drilling fluid system at oint of mixing	50 to 1000 ppm per 100 barrels of fluid	None stated
Drilling, Completion and Workover Fluids	Soluable concentrate 464-692 464-694 464-701 464-702 464-714 464-718 67869-36 59894-7 1677-206 59894-4 33753-27 33753-31	Added to fluid system	Initial: 55 to 1,666 ppm per 100 barrels of fluid Maintenance Dosage: 55 to 1,666 ppm per 100 barrels of additional fluid or as needed depending on severity of contamination	None stated
	Soluble concentrate 8133-20 464-688 33753-26	Added to fluid system	Initial: 40 to 2,000 ppm per 100 barrels of fluid. 100 to 2,000 ppm for subsequent treatment.	
	Soluble concentrate 1677-205 464-700 464-709 33753-30	Added to fluid system	33 to 3,333 ppm per 100 barrels of additional fluid or as needed depending on severity of contamination	Not for use in fracturing and completion fluids in the State of California
Packer Fluids	Soluble Concentrate 464-692 464-698 464-701 464-702 464-718 59894-7 1677-206 59894-4 33753-27 33753-31	Add at point of mixing	Add 50 to 694 ppm per 100 barrels of fluid to a freshly prepared fluids depending on severity of contamination Add 50 to 694 ppm per 100 barrels of fluid to a freshly prepared fluids depending on severity of contamination	

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Packer Fluids (cont.)	Soluble concentrate 8133-20 464-714 464-688 33753-26	Add at point of mixing	Add 90 to 1200 ppm per 100 barrels of fluid	
	Soluble concentrate 1677-205 464-700 464-709 33753-30	Add at point of mixing	Add 167 to 2,000 ppm per 100 barrels of fluid	Not for use in the State of California
Gas production and transmission pipe systems	Soluble Concentrate 464-688 464-698 464-692 464-700 464-701 464-702 464-709 464-714 464-718 1677-206 8133-20 33753-27 33753-31	Direct injection	Conduct to ensure maximum distribution of product through the entire surface of the pipeline. 56 to 667 ppm. Injections to the system should be occur weekly or as needed.	
	Soluble concentrate 1677-205 33753-30 33753-26	Direct injection	Inject 167 to 2,000 ppm into system on weekly basis or as needed to maintain control	Not for use in the State of California
Gas Storage Wells and Systems Not for use in the State of California	Soluble Concentrate 464-692 464-698 464-701	Injections	Produce a concentration of 555 to 8,300 ppm. Injections should be repeated yearly or as needed to maintain control	Injections should take place before gas is injected (during the summer)

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	404-702 464-714 464-718 1677-206 1677-205 33753-27 33753-31			Not for use in the State of California
	Soluble concentrate 8133-20 464-688 33753-26	Injections	Produce a concentration of 1,000 to 10,000 ppm. Injections should be repeated yearly or as needed to maintain control	
	Soluble concentrate 464-700 464-709 33753-30	Injections	Produce a concentration of 1,500 to 16,670 ppm. Injections should be repeated yearly or as needed to maintain control	
Hydrotesting	Soluble Concentrate 464-692 464-701 464-702 464-714 464-718 1677-206 33753-27 33753-31		Water used to hydrotest pipelines or vessels should contain 110 to 6,640 ppm per 1,000 gallons of water.	Used depending on water quality and length of time the equipment will remain idle.
Hydrotesting (cont.)	Soluble concentrate 8133-20 464-688 464-698 33753-26		Water used to hydrotest pipelines or vessels should contain 200 to 8,000 ppm per 1,000 gallons of water.	
	Soluble concentrate 1677-205 464-700 464-709		Water used to hydrotest pipelines or vessels should contain 333 to 33,333 ppm per 1,000 gallons of water.	Not for use in the State of California

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	33753-30			
Pipeline Pigging and Scraping Operations	Soluble Concentrate 464-692 464-698 464-701 464-702 464-714 464-718 1677-206 8133-20 33753-27 33753-31	Apply to slug of water immediately following the scaper	Concentration of 0.11 to 1.6% per 100 gallons of water depending on the length of the pipeline and severity of biofouling. 1,111 to 11,111 ppm per 100 gallons of water	
	Soluble concentrate 8133-20 464-688 464-700 464-709 33753-30 33753-26	Apply to slug of water immediately following the scaper	Concentration of 0.2 to 3.3% per 100 gallons of water depending on the length of the pipeline and severity of biofouling.	
Paper mills and paper mill process water systems Paper mills and paper mill process water systems (cont.)	Soluble concentrate 464-688 464-692 464-688 464-708 464-712 464-718 67869-36 1677-206 1677-205 1448-421 1448-423 1448-423 1448-429 1448-430 1448-431 1448-354 464-702 464-700 464-693	Add to the paper makng system at a point of uniform mixing such as the beaters, broke chest pump, save-all tank, or white-water tank.	Initial Dose: 0.5 – 10.0 lbs per ton of pulp or paper (dry basis) Subsequent Dose: 0.3 – 8.57 lbs per ton of pulp or paper (dry basis) Initial Dose: 0.5 – 10.0 lbs per ton of pulp or paper (dry basis) Subsequent Dose: 0.3 – 8.57 lbs per ton of pulp or paper (dry basis)	Heavily fouled systems should be boiled out prior to initial treatment. Heavily fouled systems should be boiled out prior to initial treatment.

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	464-712 464-704 464-708 33753-26 33753-27 33753-31			
Pigments and filler slurries for paper and paperboard	Soluble concentrate 464-692 464-688 464-703 464-708 464-718 67869-36 68868-2 464-693 464-704 464-688 464-712 464-708 464-703	Add to dry powder in the mixed slurry.	Use 0.10 – 2.0 lbs. per 1000 lbs. of dry powder	For use in food and non-food contact pigments and slurries
Pigments and filler slurries for paper and paperboard (cont.)	Soluble concentrate 1677-206 1667-205 1448-421 1448-422 1448-423 1448-429 1448-430 1448-431 1448-354 33753-26 33753-27 33753-31	Add to dry powder in the mixed slurry.	Use 1.1 – 20.0 lbs. of product per 10000 lbs. of slurry	For use in food and non-food contact pigments and slurries
Water based coatings for paper and paperboard	Soluble concentrate 464-692 464-688 464-703 464-708 464-712 464-718	Add to dry powder in the mixed slurry	Use 0.10 – 2.0 lbs. per 1000 lbs. of dry powder	For use in non-food contact coatings

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	68868-2 464-702 464-700 464-693 464-704 464-688 464-708 464-703 1448-354			
Water based coatings for paper and paperboard (cont.)	Soluble concentrate 1677-206 1667-205 1448-421 1448-422 1448-423 1448-429 1448-430 1448-431 33753-26 33753-27 33753-31	Add to dry powder in the mixed slurry	Use 1.0 – 20.0 lbs. of product per 10000 lbs. of slurry	For use in non-food contact coatings
Aqueous metal working fluids	Soluble concentrate 464-718 1677-206 1677-205	Add to fluid system at a point of uniform mixing.	Initial Dose: 6.7 – 84.5 lbs. per 10,000 gallons of metalworking fluid Subsequent Dose: 2.7 – 56.3 lbs. per 10,000 gallons of metalworking fluids, weekly or as needed	None stated
	Soluble concentrate 464-688 464-697 464-693 464-697 464-688	Add to fluid system at a point of uniform mixing.	Initial Dose: 4.8 – 24.6 fl. oz per 100 gallons of metalworking fluid Subsequent Dose: 1.9 – 16.4 fl. oz per 100 gallons of metalworking fluid	None stated

Glutaraldehyde Appendix A: Label Use Patterns

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble concentrate 464-692 464-698 68868-2 464-704 33753-26 33753-27 33753-31 464-698	Add to fluid system at a point of uniform mixing.	Initial Dose: 1.8 – 6 gallons per 10,000 gallons of metalworking fluid Subsequent Dose: 0.7 – 4 gallons per 10,000 gallons of metalworking fluids, weekly or as needed	None stated
Water based conveyor lubricants	Soluble concentrate 464-691 464-692 464-688 464-705 464-697 1677-206 1667-205 464-693 68868-2 464-704 33753-27 33753-31 464-688	Automated feed system.	Use a recommended automatic feed system to provide 1.3 – 28.0 fluid ounces per 100 gallons of diluted lubricant	Avoid contamination of food in application of product.
	Soluble concentrate 464-718		Use a recommended automatic feed system to provide 0.14 – 0.83 lbs. per 100 gallons of diluted lubricant	
Air washer and industrial scrubbing systems/recirculating cooling and process water systems	Soluble concentrate: 33753-30 33753-31 33753-23 33753-26 33753-27 1448-354 1448-423 1448-422 1448-421 464-707 464-688 464-764	Industrial air washer systems which have mist-eliminating components, intermittent, or continuous feed method	Initial dose: When the system is noticeably fouled, 40-80 fl oz per 1000 gallons of water to 11.5-23.0fl oz per 1000 gallons of water Subsequent Dose: When microbial control is evident 16-40 fl oz to 4.6-11.5 fl oz per 1000 gallons of water	None stated

Glutaraldehyde Appendix A: Label Use Patterns

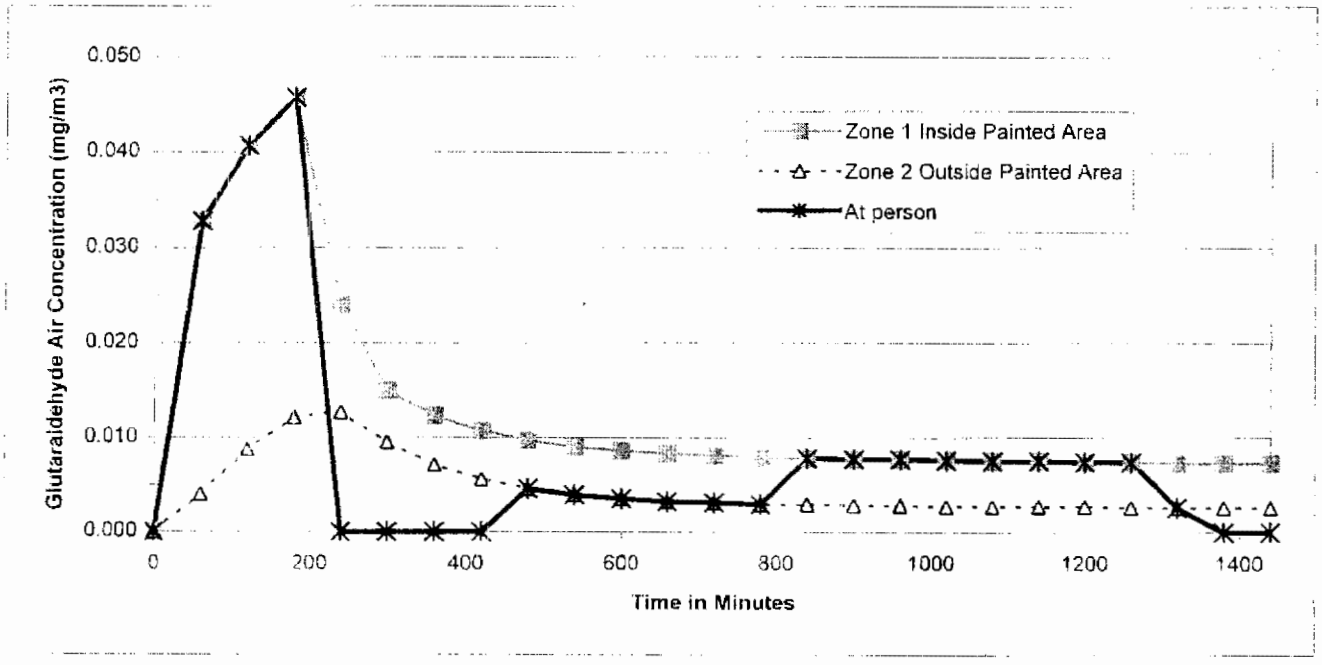
Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Air washer and industrial scrubbing systems/recirculating cooling and process water systems (cont.)	464-693 464-700 464-702 59894-4 1677-205 1677-206 464-718 59894-7 67869-36 464-692			
Service water and auxiliary systems (Fire water reserves, spray paint booths, emergency cooling water systems)	Soluble concentrate: 33753-30 33753-31 33753-23 33753-26 33753-27 464-688 464-764 464-693 464-700 464-702 1677-205 1677-206 464-718 464-692	Intermittent (slug dose) method Continuous feed method	Initial dose: 12.7 to 25.4 fl oz Per 1000 gallons of water Subsequent dose: 2.5 to 12.7 fl oz per 1000 gallons of water	None stated
Heat transfer systems (Evaporative condensers, dairy sweetwater systems, hydrostatic sterilizers , retorts, pasteurizers, warmers, once through cooling systems) Heat transfer systems (cont.)	Soluble concentrate: 33753-30 33753-31 33753-23 33753-26 33753-27 464-700 1448-354 1448-423 464-693 1448-422 1448-421 464-764 464-707 464-688	Intermittent (slug dose) method Continuous feed method	Initial dose: 12.7 to 25.4 fl oz Per 1000 gallons of water Subsequent dose: 2.5 to 12.7 fl oz per 1000 gallons of water	None stated

	59894-7 67869-36 464-692			
Industrial wastewater systems (Aerobic and anaerobic, belt pressed, digested and undigested sludge's, and holding tanks	Soluble concentrate: 33753-30 33753-31 33753-23 33753-26 33753-27 464-707 464-688 464-764 464-693 464-700 464-702 1677-205 1677-206 464-718 464-692	Add to system or sludge at convenient point of mixing such as the digester.	0.5 to 2.3 gallons per 1000 gallons of water or sludge **Macrofouling control:** ***Antimicrobial should be added continuously to*** maintain a level of 20ppm active ingredient in the system for a period of at least 96 hours 5.6fl oz per 1000 gallons water	None stated
Sugar beet mills and process water systems Sugar beet mills and process water systems	Soluble concentrate: 33753-30 33753-31 33753-23 33753-26 33753-27 464-764 464-693 464-700 1677-205 1677-206 464-692 464-704	Intermittent (slug dose) method Continuous feed method	Initial dose: 6.1 to 15.2 fl oz per ton of sliced beets to 18.3 to 45.3 fl oz per ton of sliced beets Subsequent dose: 0.9 to 9.1 fl oz per ton of sliced beets to 2.7 to 27.3 fl oz per ton of sliced beets	None stated

Appendix B - Spreadsheet for Table 9 of the Glutaraldehyde ORE Assessment

Residential Painter Inhalation Exposure to Glutaraldehyde in Treated Paint (100 ppm)

Time (days)	Time (min)	Conc Outdoors (mg/m^3)	Conc Zone 1 (mg/m^3)	Conc Zone 2 (mg/m^3)	Conc@Person (mg/m^3)
0.38	0	0.0000	0.0000	0.0000	0.0000
0.42	60	0.0000	0.0328	0.0040	0.0328
0.46	120	0.0000	0.0407	0.0087	0.0407
0.50	180	0.0000	0.0457	0.0121	0.0457
0.54	240	0.0000	0.0240	0.0127	0.0000
0.58	300	0.0000	0.0150	0.0095	0.0000
0.63	360	0.0000	0.0123	0.0071	0.0000
0.67	420	0.0000	0.0107	0.0056	0.0000
0.71	480	0.0000	0.0097	0.0046	0.0046
0.75	540	0.0000	0.0090	0.0039	0.0039
0.79	600	0.0000	0.0086	0.0035	0.0035
0.83	660	0.0000	0.0083	0.0032	0.0032
0.88	720	0.0000	0.0081	0.0031	0.0031
0.92	780	0.0000	0.0079	0.0029	0.0029
0.96	840	0.0000	0.0078	0.0029	0.0078
1.00	900	0.0000	0.0077	0.0028	0.0077
1.04	960	0.0000	0.0077	0.0028	0.0077
1.08	1020	0.0000	0.0076	0.0027	0.0076
1.13	1080	0.0000	0.0075	0.0027	0.0075
1.17	1140	0.0000	0.0075	0.0027	0.0075
1.21	1200	0.0000	0.0074	0.0027	0.0074
1.25	1260	0.0000	0.0074	0.0026	0.0074
1.29	1320	0.0000	0.0073	0.0026	0.0026
1.33	1380	0.0000	0.0073	0.0026	0.0000
1.38	1440	0.0000	0.0073	0.0026	0.0000
24 hr Average ($mg/m3$)			0.013	0.0046	0.0089
24 hr Average (ppb)			**3.3**	**1.1**	**2.2**



WPEM MODEL INPUTS

3/29/06

File with Concentration Details: C:\Program Files\wpem\Glutaraldehyde resdiy.CSV

Title of Run: Table 9 - Short Term Inhalation Risk for Residential Painters

Notes: One bedroom painted in 3.42 hours by one DIY painter (RESDIY Default Scenario)

Length of Model Run: 1 Days

Reporting Interval: 1 minutes

Type of Building: House

Air Exchange Rate: 0.45 air changes per hour

Volume: 15583 ft³

Interzonal Airflow Rate: 3451.63 ft³/hour

Percent Painted: 10.0 %

Loading Ratio: 0.29 ft²/ft²

Painted Surface Area: 451.91 ft²

Coverage:(ft²/gal)	Primer: 200	Paint: 400
Gallons of Paint:	Primer: 0.00	Paint: 1.13
Painting Hours:	Primer: 0.00	Paint: 3.42
Work Hours:	Primer: 8.0	Paint: 8.0
Painting Days:	Primer: 0	Paint: 1
Start Day:	Monday	
Type of Paint:	Latex Flat	
Density (grams/gal):	Primer: 4600.00	Paint: 4600.00
Chemical Name:	glutaraldehyde	
Molecular Weight:	100.0 g/mole	Vapor Pressure: 0.10 torr
Weight Fraction:	Primer: 0.000100	Paint: 0.000100
Emissions Model:	Primer: Empirical	Paint: Empirical
Chemical Mass (grams):	Primer: 0.00	Paint: 0.13
%Mass 1st Exponential:	Primer: 10.00	Paint: 10.00
Rate Constant 1st Exp:	Primer: 23.32500	Paint: 23.32500
Rate Constant 2nd Exp:	Primer: 0.00584	Paint: 0.00584

Indoor Sinks Model: No Sink

WPEM MODEL INPUTS (continued)

3/29/06

Exposed Individual: Do-it-Yourself Painter

Gender: Non-Specific

Location During Painting: In painted area

Weekday Pattern

	Zone	Enter Hr	Enter Min	Breathing Rate (m³/day)
Line 1	1	0	0	9.6
Line 2	2	7	0	24.0
Line 3	0	8	0	13.3
Line 4	2	16	0	18.0
Line 5	1	22	0	12.0

Weekend Pattern

	Zone	Enter Hr	Enter Min	Breathing Rate (m³/day)
Line 1	1	0	0	9.6
Line 2	2	7	30	24.0
Line 3	0	9	30	13.3
Line 4	2	16	0	18.0
Line 5	1	22	0	12.0

Breathing Rate During Painting: 27.5 m³/day

Lifetime Exposure Events: 27375

Years in Lifetime: 75

Avg. Body Weight: 71.8 kg

WPEM MODEL RESULTS

LADD: 2.60E-003 mg/kg-days	LADC: 8.91E-003 mg/m³	-or-	2.18E-003 ppm
ADD: 2.59E-003 mg/kg-days	ADC: 8.90E-003 mg/m³	-or	2.18E-003 ppm
APDR: 2.60E-003 mg/kg-days	Cpeak: 4.74E-002 mg/m³	-or-	1.16E-002 ppm
APDR Time: 1.33E+000 days	C15-min: 4.69E-002 mg/m³	-or-	1.15E-002 ppm
Single Event Dose: 1.66E-001 mg	C8-hour: 1.57E-002 mg/m³	-or-	3.84E-003 ppm

LADD = Lifetime average daily dose

ADD = Average daily dose

APDR = Acute Potential Dose Rate (highest 24-hour dose rate for exposed individual)

LADC = Lifetime average daily concentration

ADC = Average daily concentration

Cpeak = highest instantaneous concentration to which individual is exposed

C15-min = highest 15-minute average concentration to which an individual is exposed

C8-hour = highest 8-hour average concentration to which individual is exposed

Table 10 - Short Term Risks for Laundry Detergent Handlers

CEM Inputs		ID Number: Table 10	
Product: Laundry Detergent		Chemical Name: Glutaraldehyde	
Scenario: Laundry Detergent		Population: Adult	
Molecular Weight (g/mole):	100	Vapor Pressure (torr):	0.1
Weight Fraction - Median (unitless):	0.001	Weight Fraction - 90% (unitless):	0.001
Inhalation Inputs			
Frequency of Use (events/yr):	365	Years of Use:	75
Mass of Product Used per Event - Median (g):	400	Mass of Product Used per Event -90% (g):	400
Inhalation Rate During Use (m^3/hr):	0.55	Duration of Use - Median (hours/event):	0.667
Inhalation Rate After Use (m^3/hr):	0.55	Duration of Use - 90% (hours/event):	0.667
Zone 1 Volume (m^3):	20	Whole House Volume (m^3):	369
Air Exchange Rate (air exchanges/hr):	0.45	Body Weight (kg):	71.8
Activity Patterns			
User:	111111123554246742274441 1	Start Time: 9	
Non-User:		Room of Use: 5. Utility Room	
Hour:	0 6 12 18		

CEM Inhalation Exposure Estimates

ID Number: Table 10

Scenario: Laundry Detergent	Population: Adult
Inhalation Rate (m^3/day): 0.55	Years of Use (years): 75
Body Weight (kg): 71.8	Frequency of Use (events/year): 365

Exposure Units	Result	AT (days)
Chronic Cancer		
$LADD_{pot}$ (mg/kg-day)	1.97e-03	2.74e+04
$LADC_{pot}$ (mg/m^3)	1.07e-02	2.74e+04
Chronic Non-Cancer		
ADD_{pot} (mg/kg-day)	1.97e-03	2.74e+04
ADC_{pot} (mg/m^3)	1.07e-02	2.74e+04
Acute		
ADR_{pot} (mg/kg-day)	1.97e-03	1.00e+00
Cp_{pot} (mg/m^3)	2.75e-01	1.00e+00

LADD - Lifetime Average Daily Dose (mg/kg-day)

LADC - Lifetime Average Daily Concentration (mg/m^3)

ADD - Average Daily Dose (mg/kg-day)

ADC - Average Daily Concentration (mug/m^3)

ADR - Acute Dose Rate (mg/kg-day)

Cp - Peak Concentration (mg/m^3)

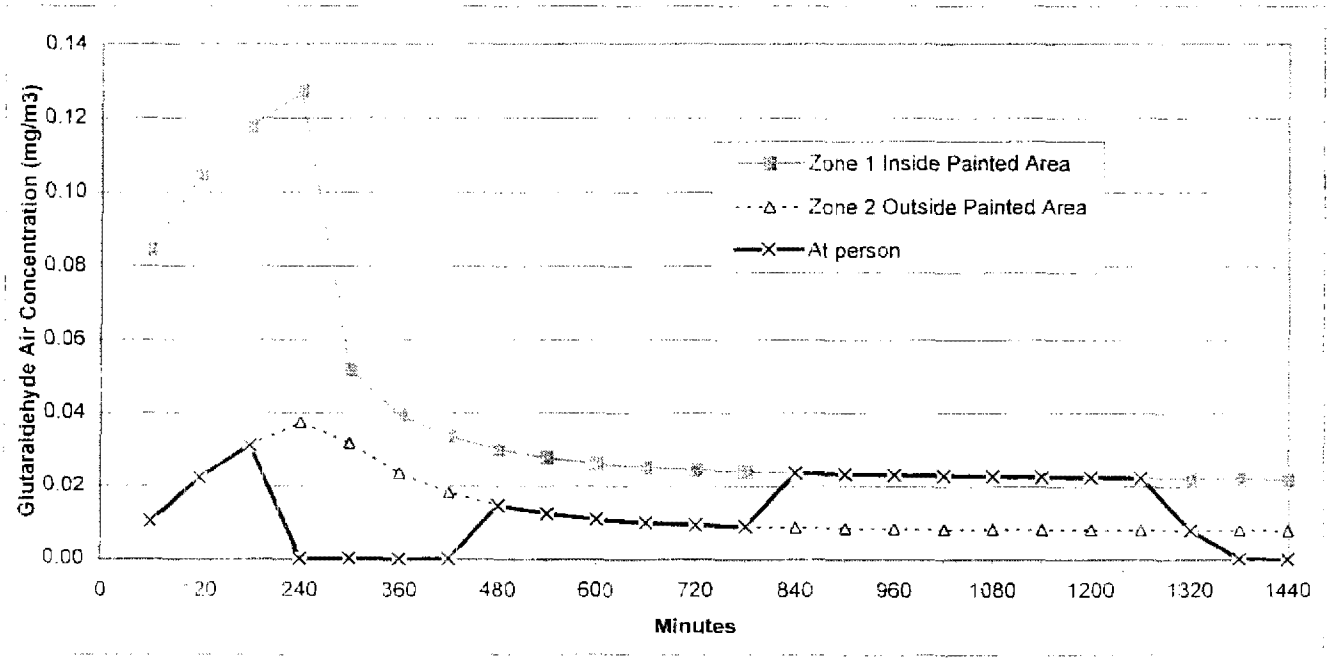
Note: 75 years = 2.738e+04 days

pot - potential dose

Note: The general Agency guidance for assessing short-term, infrequent events (for most chemicals, an exposure of less than 24 hours that occurs no more frequently than monthly) is to treat such events as independent, acute exposures rather than as chronic exposure. Thus, estimates of long-term average exposure like ADD or ADC may not be appropriate for use in assessing risks associated with this type of exposure pattern. (Methods for Exposure-Response Analysis for Acute Inhalation Exposure to Chemicals (External Review Draft). EPA/600/R-98/051. April 1998

Appendix B - Spreadsheet for Table 12 of the Glutaraldehyde ORE Assessment
Glutaraldehyde Post Application Exposure from Treated Paint (100 ppm)

Time (days)	Time (Minutes)	Conc Outdoors (mg/m^3)	Conc Zone 1 (mg/m^3)	Conc Zone 2 (mg/m^3)	Conc @ Person (mg/m3)
0.38	0	0	0	0	0
0.42	60	0.000	0.084	0.010	0.010
0.46	120	0.000	0.105	0.022	0.022
0.50	180	0.000	0.118	0.031	0.031
0.54	240	0.000	0.127	0.037	0.000
0.58	300	0.000	0.052	0.032	0.000
0.63	360	0.000	0.039	0.024	0.000
0.67	420	0.000	0.034	0.018	0.000
0.71	480	0.000	0.030	0.015	0.015
0.75	540	0.000	0.028	0.012	0.012
0.79	600	0.000	0.026	0.011	0.011
0.83	660	0.000	0.025	0.010	0.010
0.88	720	0.000	0.024	0.009	0.009
0.92	780	0.000	0.024	0.009	0.009
0.96	840	0.000	0.024	0.009	0.024
1.00	900	0.000	0.023	0.008	0.023
1.04	960	0.000	0.023	0.008	0.023
1.08	1020	0.000	0.023	0.008	0.023
1.13	1080	0.000	0.023	0.008	0.023
1.17	1140	0.000	0.023	0.008	0.023
1.21	1200	0.000	0.022	0.008	0.022
1.25	1260	0.000	0.022	0.008	0.022
1.29	1320	0.000	0.022	0.008	0.008
1.33	1380	0.000	0.022	0.008	0.000
1.38	1440	0.000	0.022	0.008	0.000
24 Hour Average (mg/m3)			0.040	0.014	0.015
24 Hour Average (ppm)			0.0097	0.0033	0.0037
24 Hour Average (ppb)			**9.7**	**3.3**	**3.7**



WPEM MODEL INPUTS

4/24/06

File with Concentration Details: C:\Program Files\wpem\Glutaraldehyde Post Ap Paint.CSV

Title of Run: Table 12 - Glutaraldedhyde Post Application Exposure from Treated Paint Applied by a Professional Painter

Notes: One bedroom painted in 3.99 hours by one professional painter (RESADULT Default Scenario)

Length of Model Run: 1 Days

Reporting Interval: 1 minutes

Type of Building: House

Air Exchange Rate: 0.45 air changes per hour

Volume: 15583 ft³

Interzonal Airflow Rate: 3451.63 ft³/hour

Percent Painted: 10.0 %

Loading Ratio: 0.29 ft²/ft²

Painted Surface Area: 451.91 ft²

Coverage:(ft²/gal)	Primer: 200	Paint: 400
Gallons of Paint:	Primer: 2.26	Paint: 1.13
Painting Hours:	Primer: 2.66	Paint: 1.33
Work Hours:	Primer: 8.0	Paint: 8.0
Painting Days:	Primer: 1	Paint: 1
Start Day:	Monday	
Type of Paint:	Latex Flat	
Density (grams/gal):	Primer: 4600.00	Paint: 4600.00
Chemical Name:	glutaraldehyde	
Molecular Weight:	100.0 g/mole	Vapor Pressure: 0.10 torr
Weight Fraction:	Primer: 0.000100	Paint: 0.000100
Emissions Model:	Primer: Empirical	Paint: Empirical
Chemical Mass (grams):	Primer: 0.26	Paint: 0.13
%Mass 1st Exponential:	Primer: 10.00	Paint: 10.00
Rate Constant 1st Exp:	Primer: 23.32500	Paint: 23.32500
Rate Constant 2nd Exp:	Primer: 0.00584	Paint: 0.00584

Indoor Sinks Model: No Sink

Table 12.

WPEM MODEL INPUTS (continued)

4/24/06

Exposed Individual: Adult

Gender: Non-Specific

Location During Painting: In building

Weekday Pattern

	Zone	Enter Hr	Enter Min	Breathing Rate (m^3/day)
Line 1	1	0	0	9.6
Line 2	2	7	0	24.0
Line 3	3	8	0	13.3
Line 4	2	16	0	18.0
Line 5	1	22	0	12.0

Weekend Pattern

	Zone	Enter Hr	Enter Min	Breathing Rate (m^3/day)
Line 1	1	0	0	9.6
Line 2	2	7	30	24.0
Line 3	3	9	30	13.3
Line 4	2	16	0	18.0
Line 5	1	22	0	12.0

Breathing Rate During Painting: 18.0 m^3/day

Lifetime Exposure Events: 18250

Years in Lifetime: 75

Avg. Body Weight: 71.8 kg

WPEM MODEL RESULTS

LADD: 1.94E-003 mg/kg-days	LADC: 1.01E-002 mg/m^3	-or-	2.48E-003 ppm
ADD: 2.90E-003 mg/kg-days	ADC: 1.52E-002 mg/m^3	-or	3.72E-003 ppm
APDR: 2.91E-003 mg/kg-days	Cpeak: 3.73E-002 mg/m^3	-or-	9.12E-003 ppm
APDR Time: 1.33E+000 days	C15-min: 3.66E-002 mg/m^3	-or-	8.94E-003 ppm
Single Event Dose: 2.09E-001 mg	C8-hour: 2.29E-002 mg/m^3	-or-	5.60E-003 ppm

LADD = Lifetime average daily dose

ADD = Average daily dose

APDR = Acute Potential Dose Rate (highest 24-hour dose rate for exposed individual)

LADC = Lifetime average daily concentration

ADC = Average daily concentration

Cpeak = highest instantaneous concentration to which individual is exposed

C15-min = highest 15-minute average concentration to which an individual is exposed

C8-hour = highest 8-hour average concentration to which individual is exposed

Appendix B - Spreadsheet for Table 17 of the Glutaraldehyde ORE Assessment

Glutaraldehyde Air Concentrations During Professional Painting of a Residence (1000 ppm)

Time (days)	Time (minutes)	Conc Outdoors (mg/m^3)	Conc Zone 1 (mg/m^3)	Conc@Person (mg/m^3)
0.38	0	0.000	0.00	0.00
0.42	60	0.000	0.75	0.75
0.46	120	0.000	1.30	1.30
0.50	180	0.000	1.68	1.68
0.54	240	0.000	1.97	1.97
0.58	300	0.000	2.19	2.19
0.63	360	0.000	2.37	2.37
0.67	420	0.000	2.52	2.52
0.71	480	0.000	2.66	2.66
0.75	540	0.000	2.78	2.78
0.75	541	0.000	2.79	2.79
0.77	563	0.000	2.83	2.83

8 hour average beginning at minute 0	**1.77**	**mg/m3**	**0.43**	**ppm**
8 hour average beginning at minute 83	**2.16**	**mg/m3**	**0.53**	**ppm**

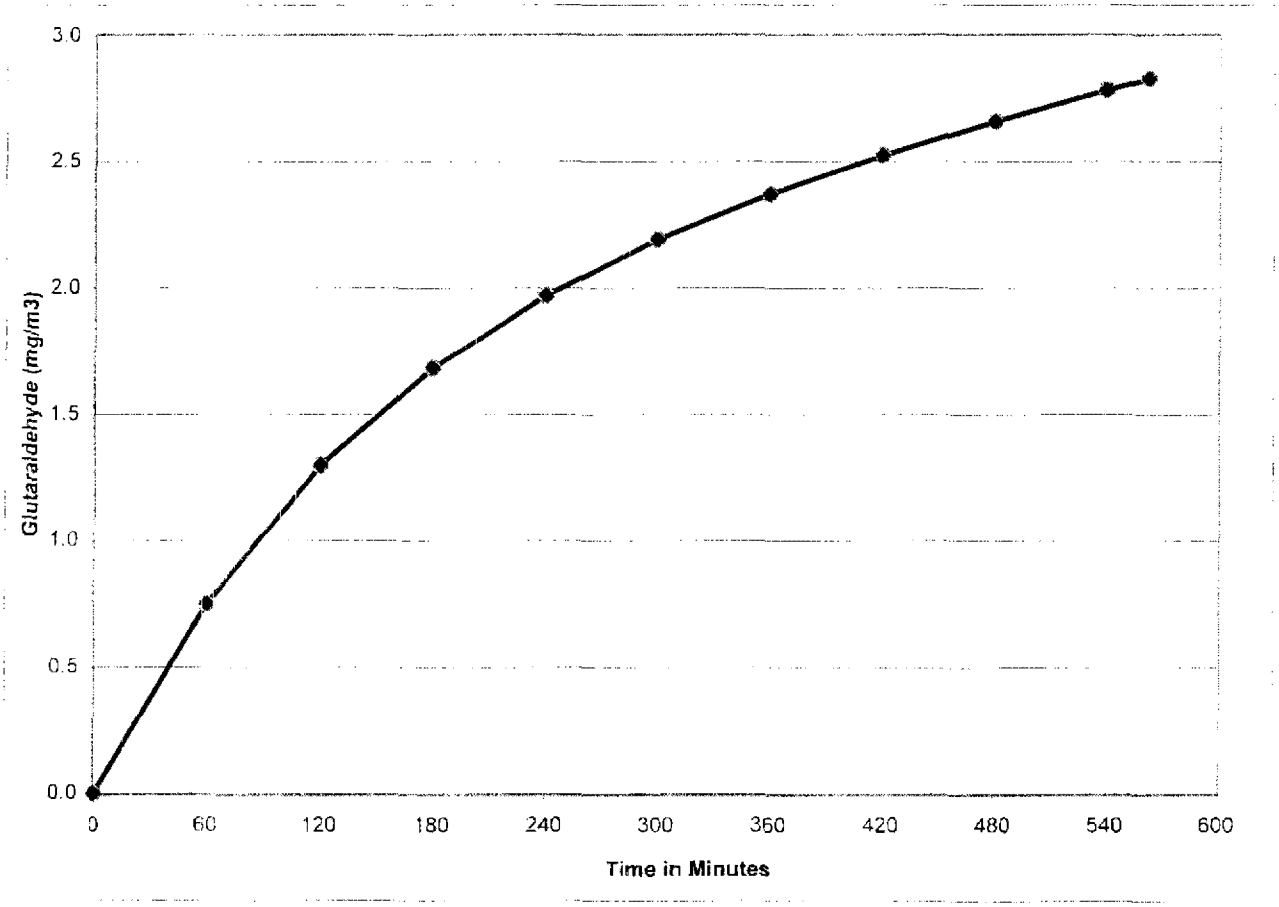


Table 17

WPEM MODEL INPUTS

4/24/06

File with Concentration Details: C:\Program Files\wpem\glutaraldehyde resprof.CSV

Title of Run: Table 17 - Inhalation Risk Summary for Occupational Painters

Notes: RESPROF Default Scenario -Entire apartment painted in one day (9.4 hours) by two professionals

Length of Model Run: 1 Days	Reporting Interval: 1 minutes
Type of Building: Apartment	Air Exchange Rate: 0.45 air changes per hour
Volume: 7350 ft³	Interzonal Airflow Rate: 1628.03 ft³/hour
Percent Painted: 100.0 %	Loading Ratio: 0.29 ft²/ft³
Painted Surface Area: 2131.50 ft²	

Coverage:(ft²/gal)	Primer: 200	Paint: 400
Gallons of Paint:	Primer: 10.66	Paint: 5.33
Painting Hours:	Primer: 6.27	Paint: 3.13
Work Hours:	Primer: 10.0	Paint: 10.0
Painting Days:	Primer: 2	Paint: 1
Start Day:	Monday	
Type of Paint:	Latex Flat	
Density (grams/gal):	Primer: 4600.00	Paint: 4600.00
Chemical Name:	glutaraldehyde	
Molecular Weight:	100.0 g/mole	Vapor Pressure: 0.10 torr
Weight Fraction:	Primer: 0.001000	Paint: 0.001000
Emissions Model:	Primer: Empirical	Paint: Empirical
Chemical Mass (grams):	Primer: 12.26	Paint: 6.13
%Mass 1st Exponential:	Primer: 10.00	Paint: 10.00
Rate Constant 1st Exp:	Primer: 23.32500	Paint: 23.32500
Rate Constant 2nd Exp:	Primer: 0.00584	Paint: 0.00584

Indoor Sinks Model: No Sink

Table 17

WPEM MODEL INPUTS (continued)

4/24/06

Exposed Individual: Professional Painter

Gender: Non-Specific

Location During Painting: In painted area

Weekday Pattern

	Zone	Enter Hr	Enter Min	Breathing Rate (m^3/day)
Line 1	0	0	0	13.3

Weekend Pattern

	Zone	Enter Hr	Enter Min	Breathing Rate (m^3/day)
Line 1	0	0	0	13.3

Breathing Rate During Painting: 27.5 m^3/day

Lifetime Exposure Events: 27375

Years in Lifetime: 75

Avg. Body Weight: 71.8 kg

WPEM MODEL RESULTS

LADD: 2.87E-001 mg/kg-days	LADC: 7.50E-001 mg/m^3	-or-	1.83E-001 ppm
ADD: 2.87E-001 mg/kg-days	ADC: 7.50E-001 mg/m^3	-or	1.83E-001 ppm
APDR: 2.87E-001 mg/kg-days	Cpeak: 2.83E+000 mg/m^3	-or-	6.92E-001 ppm
APDR Time: 7.92E-001 days	C15-min: 2.82E+000 mg/m^3	-or-	6.89E-001 ppm
Single Event Dose: 2.06E+001 mg	C8-hour: 2.16E+000 mg/m^3	-or-	5.28E-001 ppm

LADD = Lifetime average daily dose

ADD = Average daily dose

APDR = Acute Potential Dose Rate (highest 24-hour dose rate for exposed individual)

LADC = Lifetime average daily concentration

ADC = Average daily concentration

Cpeak = highest instantaneous concentration to which individual is exposed

C15-min = highest 15-minute average concentration to which an individual is exposed

C8-hour = highest 8-hour average concentration to which individual is exposed

CEM Inputs

In Num: Table 18

Product: Medical Hard Surface Cleaner Chemical Name: Glutaraldehyde

Scenario: General Purpose Cleaner Population: Adult

Molecular Weight (g/mole)	100	VP (torr)	0.1
WF - Med	0.00275	WF - 90%	0.00275

Inhalation Inputs

Frequency of Use (events/yr)	365	Years of Use	75
Mass of Product Used - Median (g)	123	Mass of Product Used - 90% (g)	123
Inhalation Rate During Use (m3/hr)	0.55	Inhalation Rate After Use (m3/hr)	0.55
Zone 1 Volume (m3)	20	Whole House Volume (m3)	369
Duration of Use - Median (hrs/ev)	1.42	Duration of Use - 90% (hrs/ev)	1.42
Air Exchange Rate (air xchgs/hr)	0.45	Body Weight (kg)	71.8

Activity Patterns

User:	1 1 1 1 1 1 1 2 2 1 5 4 2 4 6 7 4 2 2 7 4 4 4 1	Start Time:	7
Non-User:	1 1 1 1 1 1 1 1 3 2 4 4 2 4 7 7 4 2 2 7 4 4 4 1	Room of Use:	2. Kitchen
Hour:	0 6 12 18		

Dermal Inputs

Frequency of Use - Body (events/yr)	365	SA/BW - Body (cm2/kg)	15.6

Amount Retained/Absorbed to Skin (g/cm2-event) 3.6e-05

Averaging Time, $LADD_{po}$, $LADC_{pot}$	2.74e+04	Averaging Time, ADD_{pot}, ADC_{pot}	2.74e+04
Averaging Time, ADR, Cp	1.00e+00		

Table 19 - 0.45 ACH

CEM Inhalation Exposure Estimates

ID Num: Table 18 Product: Medical Hard Surface Cleaner

Scenario: General Purpose Cleaner Population: Adult

Inhalation Rate(m3/hr) 0.55 Years of Use(years) 75
BodyWeight (kg) 71.8 Frequency of Use (events/year) 365

Exposure Units	Result	AT (days)
Chronic, Cancer		
$LADD_{pot}$ (mg/kg-day)	1.97e-02	2.74e+04
$LADC_{pot}$ (mg/m3)	1.07e-01	2.74e+04
Chronic Non-Cancer		
ADD_{pot} (mg/kg-day)	1.97e-02	2.74e+04
ADC_{pot} (mg/m3)	1.07e-01	2.74e+04
Acute		
ADR_{pot} (mg/kg-day)	1.87e-02	1.00e+00
Cp_{pot} (mg/m3)	5.20e-01	1.00e+00

LADD - Lifetime Average Daily Dose (mg/kg-day)
ADD - Average Daily Dose (mg/kg-day)
ADR - Acute Dose Rate (mg/kg-day)
Note: 75 years = 2.738e+04 days

LADC - Lifetime Average Daily Concentration (mg/m3)
ADC - Average Daily Concentration (mg/m3)
Cp - Peak Concentration (mg/m3)
pot - potential dose

Note: The general Agency guidance for assessing short-term, infrequent events (for most chemicals, an exposure of less than 24 hours that occurs no more frequently than monthly) is to treat such events as independent, acute exposures rather than as a chronic exposure. Thus, estimates of long-term average exposure like ADD or ADC may not be appropriate for use in assessing risks associated with this type of exposure pattern. (Methods for Exposure-Response Analysis for Acute Inhalation Exposure to Chemicals (External Review Draft). EPA/600/R-98/051. April 1998

Table 4 - 2.0 ADH

CEM Inputs

ID Num: Table 18

Product: Medical Hard Surface Cleaner Chemical Name: Glutaraldehyde

Scenario: General Purpose Cleaner Population: Adult

Molecular Weigh: (g/mole)	100	VP (torr)	0.1
WF - Med	0.00275	WF - 90%	0.00275

Inhalation Inputs

Frequency of Use (events/yr)	365	Years of Use	75
Mass of Product Used - Median (g)	123	Mass of Product Used - 90% (g)	123
Inhalation Rate During Use (m3/hr)	0.55	Inhalation Rate After Use (m3/hr)	0.55
Zone 1 Volume (m3)	20	Whole House Volume (m3)	369
Duration of Use - Median (hrs/ev)	1.42	Duration of Use - 90% (hrs/ev)	1.42
Air Exchange Rate (air xchgs/hr)	4	Body Weight (kg)	71.8

Activity Patterns

User: 1 1 1 1 1 1 1 2 2 1 5 4 2 4 6 7 4 2 2 7 4 4 4 1 Start Time: 7

Non-User: 1 1 1 1 1 1 1 1 3 2 4 4 2 4 7 7 4 2 2 7 4 4 4 1 Room of Use: 2. Kitchen

Hour: 0 6 12 18

Dermal Inputs

Frequency of Use - Body (events/yr)	365	SA/BW - Body (cm2/kg)	15.6

Amount Retained/Absorbed to Skin (g/cm2-event) 3.6e-05

Averaging Time, $LADD_{po}$, $LADC_{pot}$	2.74e+04	Averaging Time, ADD_{pot}, ADC_{pot}	2.74e+04
Averaging Time, ADR, Cp	1.00e+00		

TABLE 9 - TC ACT

CEM Inhalation Exposure Estimates

ID Num: Table 18 Product: Medical Hard Surface Cleaner

Scenario: General Purpose Cleaner Population: Adult

Inhalation Rate(m3/hr) 0.55 Years of Use(years) 75
Body Weight (kg) 71.8 Frequency of Use (events/year) 365

Exposure Units	Result	AT (days)
Chronic, Cancer		
$LADD_{pot}$ (mg/kg-day)	2.50e-03	2.74e+04
$LADC_{pot}$ (mg/m3)	1.36e-02	2.74e+04
Chronic Non-Cancer		
ADD_{pot} (mg/kg-day)	2.50e-03	2.74e+04
ADC_{pot} (mg/m3)	1.36e-02	2.74e+04
Acute		
ADR_{pot} (mg/kg-day)	2.41e-03	1.00e+00
Cp_{pot} (mg/m3)	8.44e-02	1.00e+00

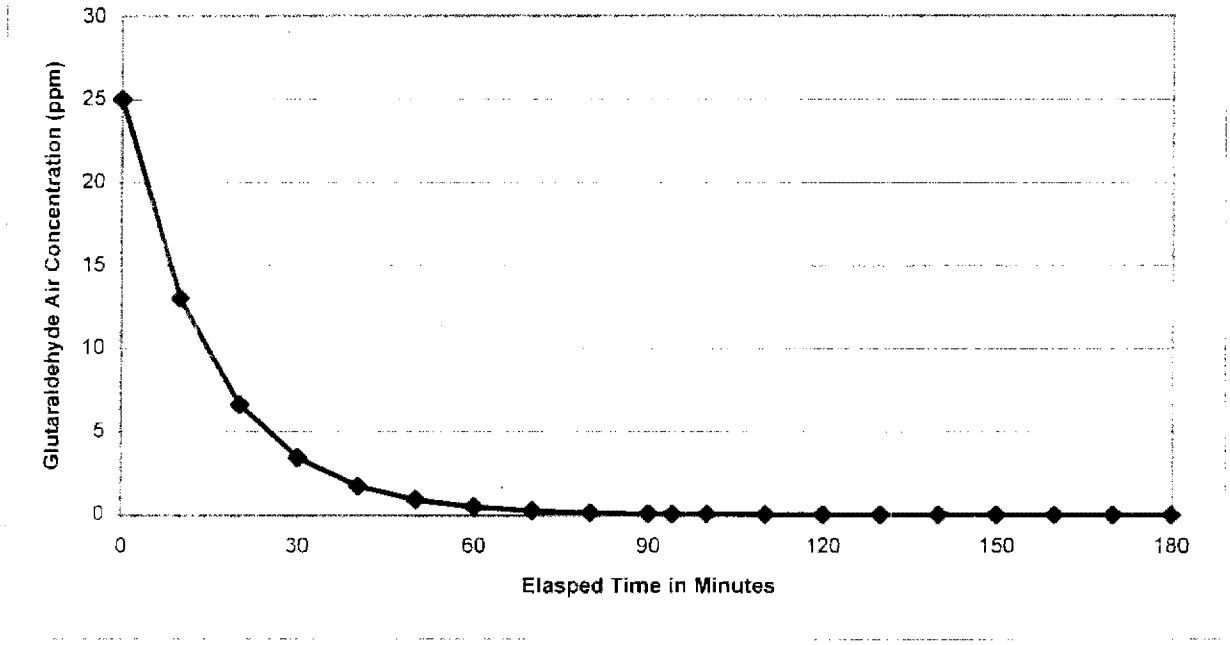
LADD - Lifetime Average Daily Dose (mg/kg-day)
ADD - Average Daily Dose (mg/kg-day)
ADR - Acute Dose Rate (mg/kg-day)
Note: 75 years = 2.738e+04 days

LADC - Lifetime Average Daily Concentration (mg/m3)
ADC - Average Daily Concentration (mg/m3)
Cp - Peak Concentration (mg/m3)
pot - potential dose

Note: The general Agency guidance for assessing short-term, infrequent events (for most chemicals, an exposure of less than 24 hours that occurs no more frequently than monthly) is to treat such events as independent, acute exposures rather than as a chronic exposure. Thus, estimates of long-term average exposure like ADD or ADC may not be appropriate for use in assessing risks associated with this type of exposure pattern. (Methods for Exposure-Response Analysis for Acute Inhalation Exposure to Chemicals (External Review Draft). EPA/600/R-98/051. April 1998

Appendix B - Spreadsheet for Table 19 of the Glutaraldehyde ORE Assessment
Glutaraldehyde Air Concentrations Following Poultry Barn Fogging

Time (minutes)	Glutaraldehyde Air Concentration (ppm)	Building Volume (cubic feet)	Ventilation Rate (cfm)	Ventilation Rate (ACH)
0	25	150000	10000	4
10	13			
20	6.6			
30	3.4			
40	1.7			
50	0.89			
60	0.46			
70	0.23			
80	0.12			
90	0.062			
94	0.047			
100	0.032			
110	0.016			
120	0.0084			
130	0.0043			
140	0.0022			
150	0.0011			
160	0.00058			
170	0.0003			
180	0.00015			



Appendix B -
Glutaraldehyde ORE Assessment
Model Runs and Spreadsheets

Note: The table numbers in this appendix correspond to the table numbers in the text of the ORE Assessment.

13544

R126955

Chemical: Glutaraldehyde

PC Code:
043901

HED File Code: 12000 Exposure Reviews
Memo Date: 4/26/2006
File ID: DPD324565
Accession #: 412-06-0194

HED Records Reference Center
7/27/2006