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

August 1, 2006

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

MEMORANDUM

SUBJECT: Occupational and Residential Exposure Assessment for Didecyl dimethyl ammonium carbonate (DDACarbonate) and didecyl dimethyl ammonium bicarbonate (DDABicarbonate) in Carboserve end-use product

From: Siroos Mostaghimi, Senior Scientist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

To: Velma Noble, PM 31
Regulatory Management Branch I
Antimicrobials Division (7510P)

Thru: Norm Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

DP Barcode (s): 321231

Pesticide Chemical No.: 069208

Registrant: Lonza Inc.

Attached please find the occupational and residential exposure assessment for the new uses of Carboserve which are submitted by Lonza Inc for registration.

EXECUTIVE SUMMARY

This document presents the occupational and residential exposure assessment for *Carboserve* which contains the preservative DDACarbonate/DDABicarbonate (50% a.i.). It addresses the potential risks to humans that result from the use of the chemical in occupational and residential settings.

Carboserve can be used as a preservative in oil field flood water systems (This scenario has already been assessed in Dideeyl Dimethyl Ammonium Chloride **(DDAC)** RED), industrial and household cleaners, paints, and air deodorizers (This scenario has been assessed in DDAC RED under trigger pump sprayer). Based on examination of product labels describing uses for the product, it has been determined that exposure to handlers can occur in occupational and residential environments. Additionally, post-application exposures to toddlers are likely to occur in residential and public access premises. The representative scenarios selected for this assessment were evaluated using maximum application rates as stated on the product label.

The routes of exposure evaluated in this assessment include: short-term (ST) dermal and short and intermediate-term (IT) oral and inhalation routes. The ST dermal NOAEL is 2 mg/kg/day, based on a 90-day rat toxicity study. The ST/IT inhalation NOAEL is 10 mg/kg/day, based on a chronic oral dog study with a 100% route-to-route absorption factor. The uncertainty factor or "target" margin of exposure (MOE) for dermal exposure is 10 and for inhalation is 100. No assessment was performed for intermediate and long term dermal and long term inhalation because of the lack of toxicity endpoints.

To assess the handler/postapplication risks, surrogate unit exposure data from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999) and the Pesticide Handlers Exposure Database (PHED) (USEPA, 1998), were used.

Residential Exposure Summary

All inhalation residential handler MOEs were above the target MOE of 100. The following short-term dermal MOE was below the target MOE of 10:

- Applying paint with an airless sprayer (MOE=9)

Occupational Exposure Summary

All short- and intermediate-term inhalation exposures were above the target MOE of 100.

The 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 DDAC that result in classification of category I, II, or III for skin irritation potential will be long-sleeved shirt, long pants, shoes, socks, chemical-resistant gloves, and a chemical-resistant apron.

1.0 INTRODUCTION

1.1 Purpose

In this document, EPA presents the results of its review of the potential human health effects of occupational and residential exposure to didecyl dimethyl ammonium carbonate/bicarbonate (DDACarbonate/DDA Bicarbonate) in a new product. This information is for use in EPA's proposed registration of a new end-use product Carboserve (DDAC/DDA Bicarbonate, 50%).

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 DDAC/DDA Bicarbonate, both criteria are met.

In this document, scenarios were assessed by using *unit exposure* data to estimate occupational and residential handlers' exposures. **Unit exposures** are estimates of the amount of exposure to an active ingredient a handler receives while performing various handler tasks and are expressed in terms of micrograms or milligrams (1mg = 1,000 µg) of active ingredient per pound of active ingredient handled. A series of unit exposures have been developed that are unique for each scenario typically considered in assessments (i.e., there are different unit exposures for different types of application equipment, job functions, and levels of protection). The *unit exposure* concept has been established in the scientific literature and also through various exposure monitoring guidelines published by the USEPA, and international organizations such as Health Canada and OECD (Organization for Economic Cooperation and Development).

Using surrogate unit exposure data, maximum application rates from the Carboserve label, and EPA estimates of daily amount handled, exposures and risks to handlers were assessed. The exposure/risks were calculated using the following equations:

Daily Exposure: Daily dermal or inhalation handler exposures are estimated for each applicable handler task with the application rate, quantity treated/handled in a day, and the applicable dermal or inhalation unit exposure using the following formula:

Daily Exposure: $E = UE \times AR \times AT$ **(Eq. 1)**

Where:

E = Amount (mg a.i./day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption;

UE = Unit exposure value (mg a.i./lb a.i.) derived from CMA data (USEPA, 1999);

AR = Maximum application rate based on a logical unit treatment, such as gallons (gal), or cubic feet (cu. ft). Maximum values are generally used (lb a.i./A, lb a.i./sq ft, lb a.i./gal, lb a.i./cu ft); and

AT = Normalized application area based on a logical unit treatment such as acres (A/day), square feet (sq ft/day), gallons (gal/day), or cubic feet (cu ft/day).

Daily Dose: The daily dermal and/or inhalation doses are calculated by normalizing the daily exposure by body weight and adjusting, if necessary, with an appropriate absorption factor. An absorption factor of 100% was used for inhalation exposures. Daily dose was calculated using the following formula:

Daily Dose: $ADD = \frac{E \times ABS}{BW}$ **(Eq. 2)**

Where:

ADD = Average daily dose received from exposure to a chemical in a given scenario (mg active ingredient/kg body weight/day);

E = Amount (mg a.i./day) deposited on the surface of the skin that is available for dermal absorption or amount inhaled that is available for inhalation absorption;

ABS = A measure of the amount of chemical that crosses a biological boundary such as lungs (% of the total available to be absorbed); and

BW = Body weight determined to represent the population of interest in a risk assessment (kg).

Margins of Exposure: Non-cancer inhalation and dermal risks for each applicable handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the daily dose to the toxicological endpoint of concern.

Margins of Exposure: $MOE = \frac{\text{NOAEL } or \text{ LOAEL}}{ADD}$ **(Eq. 3)**

Where:

MOE = Margin of exposure, value used to represent risk or how close a chemical exposure is to being a concern (unitless);

NOAEL or LOAEL = Dose level in a toxicity study, where no observed adverse effects (NOAEL) or where the lowest observed adverse effects (LOAEL) occurred in the study; and

ADD = Average daily dose or the absorbed dose received from exposure to a chemical in a given scenario (mg a.i./kg body weight/day).

A series of assumptions and exposure factors served as the basis for completing the handler risk assessment. Each general assumption and factor for both residential and occupational assessments is detailed below. Assumptions specific to the use site category are listed in the section for that specific category. The general assumptions and factors include:

- Based on the adverse effects for the endpoints, the average body weight of an adult handler (70 kg) was used to complete the non-cancer risk assessment (USEPA, 1997).

- The average body weight for a toddler of age 3 (15 kg) was used for postapplication exposures (USEPA, 1997).

- Exposure factors used to calculate daily exposures to handlers were based on applicable data, when available. When appropriate data were lacking, values from a similar scenario were used.

- The maximum application rates listed on the labels were used in this assessment.

A partial occupational/residential summary was performed by the registrant for DDACarbonate/DDA Bicarbonate for use in metal working fluids, oil field use, paints, and deodorizers (Swick, 2005). A summary of this assessment is provided in Appendix C. Although the approach used by Swick is similar to the approach used herein, it is unclear how Swick derived values for product concentrations, unit exposure values, and quantities of pesticide handled by workers.

2.-1 USE INFORMATION

2.1 Formulation Types and Percent Active Ingredient

This assessment covers uses associated with Carboserve formulated as a liquid concentrate and composed of 50% DDACarbonate/DDA Bicarbonate.

2.2 Summary of Use Pattern and Formulations

The Agency determines potential exposures to handlers of the product by identifying exposure scenarios from the various application methods that are plausible, given the label uses. The label for Carboserve provides a list of scenarios for which the product may be used (Table 2.1). Carboserve is intended for use in commercial/institutional areas (Category III), in residential/public access premises (Category IV), and in industrial oil field flood waters (Use Site Category VIII). Examples of DDACarbonate/DDA Bicarbonate uses include oil field flood water, cleaners, paints, and air deodorizers.

The label states that protective eyewear, clothing, gloves (rubber or chemical resistant), and a respirator, in the presence of the vapor, are to be worn when handling this product.

Table 2.1. Potential Use Scenarios Based on Product Labels for chemical

Use Site Category	Example Use Sites	Scenarios
Use Site Category III Commercial, institutional, and industrial premises and equipment	Formulation of metal working fluids, petroleum products, industrial cleaners, household cleaners, room deodorizers/air fresheners, paints.	• Formulation of paints through liquid pump and pour • Formulation of metal working fluids through liquid pump and pour • Brush/roller and airless sprayer applications of paints by professionals • Countertop and floor - mopping and wiping of surfaces in industrial settings (Covered in DDAC RED)
Use Site Category IV Residential and public access premises	Paints, cleaners for indoor hard surfaces.	• Brush/roller and airless sprayer applications of paints • Countertops and floors; mopping and wiping of surfaces (Covered in DDAC RED) • Post-application: dermal and incidental ingestion by toddlers (Covered in DDAC RED) • Postapplication: inhalation of air deodorizer/air freshener vapors (Covered in DDAC RED)
Use Site Category VIII Industrial Processes and Water Systems	Oil field water flood systems	• Application to petroleum flood system via liquid pump (Covered in DDAC RED)

3.0 SUMMARY OF TOXICITY CONCERNS RELATING TO EXPOSURE

3.1 Acute Toxicity

DDA Chloride's toxicity endpoints were used as surrogate endpoints for DDA Carbonate/Bicarbonate, because of the toxicity similarities between the two chemicals. The acute toxicity profile for DDAC is shown in Table 3.1. The PAN Pesticides Database lists didecyl dimethyl ammonium carbonate as the parent compound in the quaternary ammonium compounds class, and didecyl dimethyl ammonium chloride as a Group I compound under the same class, thus justifying the use of surrogate data. DDAC has moderate acute toxicity by the

oral route and low acute toxicity by the dermal route. DDAC is also a corrosive irritant to the eyes and skin. Slight skin sensitization has also been observed (USEPA, 2000).

Table 3.1. Acute Toxicity Profile for DDA Chloride		
Study Type	**Results**	**Toxicity Category**
Acute Oral	LD_{50} (carbonate) = 262 mg/kg	II
Acute Dermal	LD_{50} (combined) = 2930 mg/kg	III
Acute Inhalation	LC_{50} = between 0 - 0.7 mg/l.	II
Primary Eye Irritation	Corrosive Irritant	I
Primary Skin Irritation	Corrosive Irritant	I
Dermal Sensitization	Slight Sensitization	-

3.2 Summary of Toxicity Concerns Relating to Exposures

Table 3.2 below summarizes the toxicological endpoints for DDACarbonate/DDA Bicarbonate based on DDAC.

Table 3.2. SUMMARY OF TOXICOLOGY ENDPOINT SELECTION-DDAC

The doses and toxicological endpoints selected for DDAC are summarized below.

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	Target MOE/UF, Special FQPA SF for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13+)	**NOAEL**(developmental) = 10 mg/kg/day	**FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation)	Prenatal Developmental Toxicity - Rat MRID 41886701 **LOAEL** = 20 mg/kg/day based on increased incidence of skeletal variations.
	Acute RfD = 0.1 mg kg/day (Females age 13+)		
Acute dietary (General pop.)	an acute dietary endpoint for the general population was not identified in the database for DDAC.		

Chronic Dietary (general population)	**NOAEL** = 10 mg/kg/day	**FQPA SF** = 1 **UF** = 100 (10x inter-species extrapolation, 10x intra-species variation	Chronic Toxicity Study - Dog MRID 41970401 **LOAEL** = 20 mg/kg/day based on decreased total cholesterol levels in females.
	Chronic RfD = 0.1 mg/kg/day		
Non-Dietary Exposures			
Incidental Oral Short-Term	**NOAEL**(developmental) = 10 mg/kg/day	**UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **FQPA SF** = 1	Prenatal Developmental Toxicity - Rat MRID 41886701 **LOAEL** = 20 mg/kg/day based on increased incidence of skeletal variations.
Incidental Oral Intermediate-Term	**NOAEL** = 10 mg/kg/day	**UF** = 100 (10x inter-species extrapolation, 10x intra-species variation) **FQPA SF** = 1	Chronic Toxicity Study - Dog MRID 4197040l **LOAEL** = 20 mg/kg/day based on decreased total cholesterol levels in females.
Dermal, Short-term (formulated product, 0.13% a.i.)	No endpoint identified. No dermal or systemic effects identified in the 21-day dermal toxicity study (MRID 45656601) up to and including the limit dose of 1000 mg/kg/day		
Dermal, Short-term (TGAI 80% diluted to 0.1%)	**NOAEL(dermal)** = 2 mg/kg/day (8 µg/cm^2)	**UF** = 10 (3x inter-species extrapolation, 3x intra-species variation)	90-day Dermal Toxicity - Rat MRID 41305901 **LOAEL** = 6 mg/kg/day based on increased clinical and gross findings (erythema, edema, exfoliation, excoriation, and ulceration) beginning on day 4-5 of treatment.
Dermal, Intermediate- and Long-term (formulated product)	No appropriate endpoint identified.		
Inhalation, Short-Term	**NOAEL** = 10 mg/kg/day[a]	**UF** = 100 (10x inter-species extrapolation, 10x intra-species variation, 10x route-extrapolation) **DB UF** - an additional 10x is necessary for route extrapolation. If risk estimates are below an MOE of 1000, a confirmatory	Prenatal Developmental Toxicity - Rat MRID 41886701 **LOAEL** = 20 mg/kg/day based on increased incidence of skeletal variations.

		inhalation toxicity study may be required.	
Inhalation, Intermediate- and Long-Term	**NOAEL** = 10 mg/kg/day[a]	**UF** = 100 (10x inter-species extrapolation, 10x intra-species variation, 10x route-extrapolation) **DB UF**- an additional 10x is necessary for route extrapolation. If risk estimates are below an MOE of 1000, a confirmatory inhalation toxicity study may be required.	Chronic Toxicity Study - Dog MRID 41970401 **LOAEL** = 20 mg/kg/day based on decreased total cholesterol levels in females.

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, RfD = reference dose, MOE = margin of exposure, LOC = Level of concern, NA = Not Applicable.

[a]An additional uncertainty factor of 10x is applied for use of an oral endpoint for route-to-route extrapolation to determine if a confirmatory inhalation toxicity study is warranted.

[c] TGAI-based dermal endpoint = (2 mg/kg rat x 0.2 kg rat x 1000 ug/mg) / 50cm^2 area of rat dosed = 8 µg/cm^2 .

3.3 FQPA Considerations

Based on available data, HIARC concluded there is no evidence DDA Chloride will induce neurotoxic effects. In addition, there is no quantitative or qualitative evidence of increased susceptibility to rat or rabbit fetuses following in utero exposure in the prenatal developmental toxicity studies or in the offspring when exposed to adults in the two-generation reproductive study. HIARC concluded that the evidence does not support the need for a developmental neurotoxicity study.

4.-1 RESIDENTIAL EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Products containing Carboserve, such as paints, cleaners, and air deodorizers, can be applied by home owners and lead to dermal and inhalation short- and intermediate-term residential exposures as well as postapplication dermal, inhalation, and oral short- and intermediate-term exposures to adults and children. The exposure scenarios assessed in this document for representative uses selected by EPA are shown in Table 4.1.

Table 4.1. Representative Uses Associated with Occupational and Residential Exposure			
Representative Use	Application Method	Application Rate	Exposure Scenario Assessed
Paints (Occupational and Residential)	Brush/roller	0.125% or 1250 ppm (2500 ppm x 50% a.i)	ST/IT Secondary occupational and Residential: Adult-dermal and inhalation ST/IT Postapplication: Child-dermal and incidental ingestion (hand to mouth)
	Airless sprayer	0.125% or 1250 ppm (2500 ppm x 50% a.i)	ST/IT Secondary occupational and Residential: Adult-dermal and inhalation ST/IT Postapplication: Child-dermal and incidental ingestion (hand to mouth)

4.2 Residential Exposure/Risk Pathway

4.2.1 Residential Handler Exposure Scenarios

Handler exposures were assessed for the following scenarios:

- Dermal and inhalation exposures to paint, brush/roller
- Dermal and inhalation exposures to paint, airless sprayer

The scenarios were assessed using CMA data, PHED, and Equations 1-3 in Section 1.2, "Criteria for Conducting Risk Assessment." The assumptions and factors used for those scenarios in which CMA and PHED data were used include:

Unit Exposure Values: Unit exposure values were taken from the PHED data presented in HED's Residential SOPs (USEPA, 1997) or from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999; DP Barcode D247642).

- For the **brush/roller scenario**, PHED dermal and inhalation unit exposure values for a residential handler applying a pesticide using an airless sprayer were used. These unit exposure values (230 mg/lb a.i. for dermal and 0.284 mg/lb a.i. for inhalation) represent a handler wearing short pants and a short sleeve shirt, with no gloves.

- For the **airless sprayer scenario**, PHED dermal and inhalation unit exposure values for a residential handler applying a pesticide using an airless sprayer were used. These unit

ungloved exposure values (79 mg/lb a.i. for dermal and 0.83 mg/lb a.i. for) represent a handler wearing short pants and a short sleeve shirt, with no gloves.

Quantity Handled/Treated: The quantities handled/treated were estimated based on information from various sources, including the 2005 Antimicrobial Division Standard Operating Procedures (SOPs). It is assumed that cleaning solutions made with Carboserve have the same density as water (8.34 lbs/gal), while paints have a density of 10 lbs/gal.

- For the ***brush/roller*** in ***paint applications***, it is assumed that 20 lbs (2 gallons) of treated paint will be used. This is based on the 90th percentile value of 8 gallons of latex paint used per year divided by the mean frequency of 4 painting events/year.
- For the ***airless sprayer*** in ***paint applications***, it is assumed that 150 lbs (15 gallons) of treated paint will be used. This is based on the coverage of 200 ft^2/ gallon and a house size of 40 x 30 x 20 ft (surface area of 2,800 ft^2).

Results

The resulting short- and intermediate-term exposures and MOEs for the representative residential handler scenarios are presented in Table 4.2. The dermal MOEs (Target MOE=10) for the following scenarios were:

- Applying paint with a paint brush (MOE=24)
- Applying paint with an airless sprayer (MOE=9)

All short- and intermediate-term inhalation MOEs exceeded the target inhalation MOE of 100.

Table 4.2. Short-Term DDAC/DDA Bicarbonate Residential Handlers Exposures and MOEs

Exposure Scenario	Method of Application	Unit Exposure (mg/lb ai)		Application Rate (%)	Quantity Handled/ Treated per day (lb)[b]	Daily Dose (mg/kg/day)		MOE (ST/IT)	
		Dermal[a]	Inhalation			Dermal[c]	Inhalation[d]	Dermal[e] (Target = 10)	Inhalation[e] (Target = 100)
Painting	Brush/roller	230	0.284	0.125	20.0	.0821	1.01×10^{-4}	24	99,000
	Airless Sprayer	79.0	0.830	0.125	150	0.212	0.00222	9	4,500

a All dermal unit exposures represent ungloved replicates.

b Quantity handled/treated = gals handled/treated x 8.34 lbs/gal of product (for hard surface cleaners) or 10 lbs/gal of product (for paints)

c Dermal Daily Dose (mg/kg day) = [dermal unit exposure (mg/lb ai) * application rate * quantity handled] / body weight (70 kg).

d Inhalation Daily Dose (mg/kg/day) = [inhalation unit exposure (mg/lb ai) * application rate * quantity handled] / body weight (70 kg).

e Dermal MOE = NOAEL (2 mg/kg/day) / Daily Dose. Target dermal MOE is 10.
f Inhalation MOE = NOAEL (10 mg/kg/day) / Daily Dose. Target inhalation MOE is 100.

5.-1 OCCUPATIONAL EXPOSURE ASSESSMENT

5.1 Occupational Exposures

Carboserve used in formulations for oil field flood water systems and in paints, cleaners, and air deodorizers can lead to short- and intermediate-term dermal and inhalation occupational exposures (Use Site Categories III, IV, and VIII). The exposure scenarios assessed in this document for the representative uses selected by AD are shown in Table 5.1.

Table 5.1. Representative Uses Associated with Occupational Exposure

Representative Use	Application Method	Application Rate	Exposure Scenario Assessed
Use as material preservative for paints, petroleum products, and Industrial/household cleaning products	Metered pump (liquid)	0.125% or 1250 ppm (2500 ppm x 50% a.i)	ST/IT Handler: Adult inhalation
	Liquid pour	0.125% or 1250 ppm (2500 ppm x 50% a.i)	ST/IT Handler: Adult inhalation
Paints- Professional	Brush/roller	0.125% or 1250 ppm (2500 ppm x 50% a.i)	ST/IT Secondary Occupational: Adult inhalation
	Airless sprayer	0.125% or 1250 ppm (2500 ppm x 50% a.i)	ST/IT Secondary Occupational: Adult inhalation

The occupational scenarios described in Table 5.1 were assessed to determine inhalation exposure. The scenarios were assessed using CMA data, PHED, and Equations 1-3 in Section 1.2, "Criteria for Conducting Risk Assessment."

Unit Exposure Values: Unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999; DP Barcode D247642) or from the PHED data presented in HED's Residential SOPs (USEPA, 1997).

CMA Data were used for the following scenarios:

- For the ***liquid pour*** scenarios, data are based on measurements taken on test subjects transferring pesticide materials from large to small measuring or pouring containers. For *baseline dermal exposure (all liquid pour scenarios)*, the dermal UE is 50.3 mg/lb a.i., based on observation of one ungloved replicate working in a cooling tower. For dermal exposure associated with PPE-G use and baseline inhalation exposure, the following data were used, based on replicates wearing a single layer of clothing and chemical-resistant gloves:
  - *Metal working fluid*: data for workers handling metal fluids (8 replicates). The dermal UE is 0.184 mg/lb a.i. and the inhalation UE is 0.00854 mg/lb a.i.
  - *Preservative formulations*: data for workers handling preservatives (2 replicates). The dermal UE is 0.135 mg/lb a.i. and the inhalation UE is 0.00346 mg/lb a.i.

- For the ***liquid pump*** scenarios, data are based on measurements taken on test subjects transferring a pesticide product using gravity flow or metered pumping. For *baseline dermal exposure (all liquid pump scenarios)*, the dermal UE is 0.454 mg/lb a.i., based on observation of 1 ungloved replicate working at a cooling tower. For dermal exposure associated with PPE-G use and baseline inhalation exposure, the following data were used, based on replicates wearing a single layer of clothing and chemical-resistant gloves:
  - *Metal working fluid*: data for workers handling metal fluids (2 replicates). The dermal UE is 0.312 mg/lb a.i. and the inhalation UE is 0.00348 mg/lb a.i.
  - *Preservative formulations* : data for workers handling preservatives (2 replicates). The dermal UE is 0.00629 mg/lb a.i. and the inhalation UE is 0.000403 mg/lb a.i.

PHED data were used for the following scenarios:

- For the ***airless sprayer*** scenario, dermal and inhalation unit exposure values for a professional painter applying a pesticide using an airless sprayer were used. The baseline dermal, PPE-G dermal, and baseline inhalation unit exposure values are 38, 14, and 0.83 mg/lb a.i., respectively.

- For the ***brush/roller*** scenario, dermal and inhalation unit exposure values for a professional painter applying a pesticide using a paintbrush were used. The baseline dermal, PPE-G dermal, and baseline inhalation unit exposure values are 180, 24, and 0.28 mg/lb a.i., respectively.

Quantity handled/treated: The quantities handled/treated were estimated based on information from various sources. It is assumed that all products have the same density as water (8.34 lbs/gal).

- For the ***liquid pump*** the following quantities handled/treated were used:
  - Metal working fluid - 300 gallons (2500 lb)
  - Oil field flood water systems - 31,500 gallons.
  - Preservatives (paints/detergents/cleaners)- 20,000 gallons (200,000 lb)

- For the ***liquid pour*** the following quantities handled/treated were used:
  - Metal working fluid - 300 gallons (2500 lb)

- Preservatives (paints/detergents/cleaners)- 2,000 gallons (20,000 lb)

- For the ***airless sprayer*** in ***paint applications***, 500 lbs (approximately 50 gallons) of treated paint are used.
- For the ***brush/roller*** **in *paint applications***, 50 lbs (approximately 5 gallons) of treated paint are used.

Results

The resulting short-, intermediate-term inhalation exposures and MOEs for the representative primary and secondary handler occupational are presented in Table 5.2. All inhalation MOEs were above the target MOE of 100.

The 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 DDAC that result in classification of category I, II, or III for skin irritation potential will be long-sleeved shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron. Once diluted, if the concentration of DDAC 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.

Table 5.2. Short and Intermediate-Term Occupational Handlers Exposures and MOEs

Exposure Scenario	Method of Application	Unit Exposure (mg/lb ai)	Application Rate [a]	Quantity Handled/ Treated per day	Daily Dose (mg/kg/day)	MOE (ST/IT) (Target MOE=100)
		Baseline Inhalation			Inhalation[b]	Inhalation[c]
Preservatives (Cleaners, paints)	Liquid Pour	0.00346	0.125%	20,000 lb	0.00124	8,100
	Liquid Pump	0.00403	0.125%	2.00×10^{3} lb	0.0144	690
Preservative-Metal fluid	Liquid Pour	0.00854	0.125%	2,500 lb	3.82×10^{-4}	26,000
	Liquid Pump	0.00348	0.125%	2,500 lb	1.55×10^{-4}	64,000
Painting	Paint Brush/Roller	0.280	0.125%	50.0 lb	2.50×10^{-4}	40,000
	Airless Sprayer	0.830	0.125%	500 lb	0.00741	1,300

a See Table 4.1.

b Inhalation Daily Dose (mg/kg/day) = [inhalation unit exposure (mg/lb ai) * application rate * quantity handled] ÷ body weight (70 kg).

c Inhalation MOE = NOAEL (10 mg/kg/day) / Daily Dose. Target inhalation MOE is 100.

5.1.1 Dermal and Inhalation Exposure To Metal Working Fluids

Formulations using Carboserve as a preservative in formulations of metal working fluids can lead to short- and intermediate-term dermal and inhalation occupational exposures. These routes of exposure occur after the chemical has been incorporated into the metal working fluids and a machinist is using/handling this treated end-product, the treated fluids.

A screening-level dermal exposure estimate was derived using the 2-hand immersion model from ChemSTEER. The model is available at: www.epa.gov/opptintr/exposure/docs/chemsteer.htm. The 2-hand immersion model is as follows:

$$\text{Dermal Dose} = \frac{SA_{hand} \times \%\text{ a.i.} \times FT \times F}{BW} \qquad \textbf{(Eq. 4)}$$

Where:

SA_{hand}	=	Surface area of the hand (840 cm^2);
FT	=	Film thickness (10.3 mg/cm^2);
% a.i.	=	Percent of active ingredient in the fluid (0.125%);
F	=	Frequency of hand immersions per day (1/day); and
BW	=	Body weight (70 kg).

Assumptions

- The value for the film thickness, 10.3 mg/cm^2, represents complete immersion into the fluid with no wiping and is based on DDAC/DDA Bicarbonate dermal irritation.
- All other variables represent ChemSTEER default values.

Results

Table 5.3 shows the results of the calculation. For workers who place their hands into metal working fluids once daily, an MOE of 13 was calculated. The MOE is above the target MOE of concern (MOE=10).

Table 5.3. Short term Dermal Occupational Exposures and MOEs for Immersions of Hands in Metal Working Fluids-Adults		
Parameter	Value	Rationale
Surface area	840 cm^2	ChemSTEER default
Film thickness	10.3 mg/cm^2	USEPA
% a.i.	0.125%	Product label
Frequency	1/day	ChemSTEER default
Body weight	70 kg	USEPA, 1997
Dermal dose	0.155 mg/kg/day	Eq. 4
Dermal NOAEL	2 mg/kg/day	Dermal endpoint selected
Dermal short-term MOE	13	MOE = Dermal NOAEL (2 mg/kg/day) / potential daily dose (mg/kg/day). Target MOE = 10.

A screening-level inhalation exposure estimate for treated metal working fluids has been developed using the OSHA PEL for oil mist. The equation used for calculating the inhalation dose is:

$$\text{Inhalation Dose} = \frac{C \times IR \times \%\text{ a.i.} \times ET}{BW} \qquad \textbf{(Eq. 5)}$$

Where:

C = Oil mist concentration (5 mg/m^3);
IR = Inhalation rate (1.25 m^3/hr);
% a.i. = Percent of active ingredient in the fluid (0.125%);
ET = Exposure time (8 hrs/day); and
BW = Body weight (70 kg).

Assumptions

- The value for the concentration is the high-end oil mist concentration based on the OSHA Permissible Exposure Limit (PEL) of 5 mg/m^3
- Inhalation rate value of 1.25 m^3/hr, is based on the breathing rate of an adult (USEPA, 1997).
- Exposure time is based a typical working day (8 hours/day).

Results

The inhalation MOE for a metal working fluid worker is 11,200. The MOE is above the target MOE (MOE=100).

Table 5.4. Short- and Intermediate-term Inhalation Occupational Exposures and MOEs for Immersions of Hands in Metal Working Fluids-Adults		
Parameter	Value	Rationale
Oil mist concentration	5 mg/m^3	OSHA PEL
Inhalation rate	1.25 m^3/hr	USEPA
% a.i.	0.125%	Product label
Exposure Time	8 hr/day	
Body weight	70 kg	USEPA, 1997
Inhalation dose	0.000893 mg/kg/day	Eq. 5
Inhalation NOAEL	10 mg/kg/day	Inhalation endpoint selected
Inhalation short-, intermediate-term MOE	11,000	MOE = Inhalation NOAEL (10 mg/kg/day) / potential daily dose (mg/kg/day). Target MOE = 100.

5.2 Occupational Post-application Exposure

Occupational post-application and bystander exposures are considered to be minimal compared to handler exposures.

5.3 Data Limitations/Uncertainties

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

$ Surrogate dermal unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study (USEPA, 1999; DP Barcode D247642) and the Pesticide Handlers Exposure Database (PHED) (USEPA, 1998). See Appendix A for a summary of this data source.

$ None of the surrogate unit exposures specifically represent the treatment applications; therefore, values from a scenario deemed similar enough by the assessor were used.

$ Assumptions for the use amounts treated were based on AD estimates and could be further refined from input from registrants.

6.-1 REFERENCES

HERA, 2003. Human and Environmental Risk Assessment, Guidance Document Methodology, April 22, 2002 (http://www.heraproject.com/files/Guidancedocument.pdf).

HERA, 2005. Human and Environmental Risk Assessment, Guidance Document Methodology, February 2005 (http://www.heraproject.com).
The Multi-Chamber Concentration and Exposure Model (MCCEM) Model Version 1.2. Prepared for the US EPA Office of Pollution Prevention and Toxics. Prepared by Versar, Inc. and Wilkes Technologies, LLC.

Swick C. 2005. Exposure and Risk Assessment for the Use of Bardac 22C50 and Carboserve as an Oil-Field Biocide and Material Preservative. MRID 465784-01.

USEPA. 1986. Standard scenarios for estimating exposure to chemical substances during use of consumer products. Volume VI. Prepared by Versar Inc. for Exposure Evaluation Division, Office of Toxic Substances, US Environmental Protection Agency, Washington, DC (EPA Contract No. 68-02-3968).

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

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

USEPA. 2000. Residential SOPs. EPA Office of Pesticide ProgramsBHuman Health Effects Division. Dated April 5, 2000.

USEPA. 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.

File: C:\Myfile\2005 Reports\ Carboserv \ Occupational and Residential Exposure Assessment for Carboserv (DP321231)

CC: RASSB Chemical File
Siroos Mostaghimi, RASSB

APPENDIX A: Summary of CMA and PHED Data

Chemical Manufacturers Association (CMA) Data:

In response to an EPA Data Call-In Notice, a study was undertaken by the Institute of Agricultural Medicine and Occupational Health of The University of Iowa under contract to the Chemical Manufacturers Association. In order to meet the requirements of Subdivision U of the Pesticide Assessment Guidelines (superseded by Series 875.1000-875.1600 of the Pesticide Assessment Guidelines), handler exposure data are required from the chemical manufacturer specifically registering the antimicrobial pesticide. The applicator exposure study must comply with the assessment guidelines for AApplicator Exposure Monitoring@ in Subdivision U and the AOccupational and Residential Exposure Test Guidelines@ in Series 875. For this purpose, CMA submitted a study on 28 February 1990, entitled "Antimicrobial Exposure Assessment Study (amended on December 8, 1992)" which was conducted by William Popendorf, et al. It was evaluated and accepted by Occupational and Residential Exposure Branch (OREB) of Health Effect Division (HED), Office of Pesticides Program (OPP) of EPA in 1990. The purpose of this CMA study was to characterize exposure to antimicrobial chemicals in order to support pesticide re-registrations (CMA, 1992). The unit exposures presented in the most recent EPA evaluation of the CMA database (USEPA,, 1999) were used in this assessment.

The Agency determined that the CMA study had fulfilled the basic requirements of Subdivision U - Applicator Exposure Monitoring. The advantages of CMA data over other Asurrogate data sets@ is that the chemicals and the job functions of mixer/loader/applicator were defined based on common application methods used for antimicrobial pesticides. A few of the deficiencies in the CMA data are noted below:

- The inhalation concentrations were typically below the detection limits, so the unit exposures for the inhalation exposure route could not be accurately calculated.
- QA/QC problems including lack of either/or field fortification, laboratory recoveries, and storage stability information.
- Data have an insufficient amount of replicates.

The Pesticide Handlers Exposure Database (PHED).

The Pesticide Handlers Exposure Database (PHED) has been developed by a Task Force consisting of representatives from Health Canada, the U.S. Environmental Protection Agency (EPA), and the American Crop Protection Association (ACPA). PHED provides generic pesticide worker (i.e., mixer/loader and applicator) exposure estimates. The dermal and inhalation exposure estimates generated by PHED are based on actual field monitoring data, which are reported generically (i.e., chemical specific names not reported) in PHED. It has been the Agency=s policy to use Asurrogate@ or Ageneric@ exposure data for pesticide applicators in certain circumstances because it is believed that the physical parameters (e.g., packaging type) or application technique (e.g., aerosol can), not the chemical properties of the pesticide, attribute to exposure levels. [Note: Vapor pressures for the chemicals in PHED are in the range of E-5 to E-7 mm Hg.] Chemical specific properties are accounted for by correcting the exposure data for study specific field and laboratory recovery values as specified by the PHED grading criteria.

PHED handler exposure data are generally provided on a normalized basis for use in exposure assessments. The most common method for normalizing exposure is by pounds of active ingredient (ai) handled per replicate (i.e., exposure in mg per replicate is divided by the amount of ai handled in that particular replicate). These unit exposures are expressed as

mg/lb ai handled. This normalization method presumes that dermal and inhalation exposures are linear based on the amount of active ingredient handled.

APPENDIX B: Input/Output from Residential MCCEM Modeling

Residential Adult

MCCEM SUMMARY OF INPUTS

TITLE: MCCEM Post-application Adult Exposure to Aerosol Spray (Residential)

NOTES:

RUN	Day	Hour	Min	Length	Days	Hours	Min	Reporting
TIME Start:	0	0	0	of Run:	1	0	0	Interval: 15 minutes

HOUSE Type: Generic house State: NA Code: GN001

Season: SUMMER Zones: 2 Infiltration Rate: 0.18 ACH

EMISSIONS	Source	Zone	Type	Details
	1			
	2			
	3			
	4			

SINKS	Sink	Zone	Model	Details
	1			
	2			
	3			

4

5

6

ACTIVITIES Primary Activity Pattern is used on days: 1,2,3,4,5,6,7

OVERRIDE ACTIVITIES: YES

DOSE
Events/yr: 255 Yrs of Use: 1 Weight(kg): 70 Length of Life(yrs): 75

MONTE CARLO: NO Number of Trials: 1 Seed No: Random

OPTIONS Single Chamber: NO Saturation Concentration (mg/m^3): 0
Output Concentration Units: mg/m^3

Initial Concentrations: Units: g/m^3

Zone 1: 0.0000353 Zone 2: 0 Zone 3: 0 Zone 4: 0
Outdoors: 0

Residential Child

TITLE: MCCEM Post-application Child Exposure to Aerosol Spray (Residential)

NOTES:

RUN Day Hour Min Length Days Hours Min Reporting

TIME Start: 0 0 0 of Run: 1 0 0 Interval: 15 minutes

HOUSE Type: Generic house State: NA Code: GN001

Season: SUMMER Zones: 2 Infiltration Rate: 0.18 ACH

EMISSIONS Source Zone Type Details

1			
2			
3			
4			

SINKS Sink Zone Model Details

1			
2			
3			
4			
5			
6			

ACTIVITIES Primary Activity Pattern is used on days: 1,2,3,4,5,6,7

OVERRIDE ACTIVITIES: YES

DOSE
Events/yr: 255 Yrs of Use: 1 Weight(kg): 15 Length of Life(yrs): 75

MONTE CARLO: NO Number of Trials: 1 Seed No: Random

OPTIONS Single Chamber: NO Saturation Concentration (mg/m³): 0 Output Concentration Units: mg/m³

Initial Concentrations Units: g/m³

Zone 1: 0.0000353 Zone 2: 0 Zone 3: 0 Zone 4: 0 Outdoors: 0

APPENDIX C: Summary of Registrant Exposure Assessment (Swick, 2005)

The following is a short summary of the approach used by Swick (2005) to calculate exposures associated with metal working fluids, oil field use, paints, and deodorizers.

Inhalation: 10 mg/kg/day- short-term based on a rat developmental study; intermediate-, and long-term based on chronic dog study.

Dermal: 12 mg/kg/day; disagrees with HIARC selection of a NOAEL of 2 mg/kg/day. The NOEAL is based on a skin irritation study that is dependant on concentrations and not doses and should be based on a systemic parameter. Also the Carboserve label will require the use of gloves to reduce the risk of skin irritation.

Exposure Assessments

Metal working fluids- dermal and inhalation occupational

- **Maximum use rate of 0.25% (DDAC/DDABicarbonate)**
- **Volume is 300 gallons about 2,500 pounds**
- **Unit Exposures are based on CMA data for liquid pump and are 325 ug a.i./lb (dermal) and 1.2 ug a.i./lb (inhalation)**
- **Body weight is 70 kg**
- **Calculation: Use rate (% a.i.) x Volume treated (lbs) x Unit exposures (ug a.i./lb) / Body weight (kg)**
- **MOE (dermal and inhalation) is 413 and 100,000**

Metal working fluids- inhalation occupational post application

- Maximum use rate of 0.25% (DDAC/DDABicarbonate)
- IR for adult worker is 1.25 m^3/hr
- ET is 8 hours/day
- Oil mist concentration of 5 mg/ m^3 based on OSHA PEL
- Body weight is 70 kg
- **Calculation: Use rate (% a.i.) x Inhalation rate (m^3/hr) x Duration of exposure (hr/day) x Oil mist concentration (5 mg/ m^3)**
- **MOE (inhalation) is 5,882**

Oil Field- dermal occupational

- **Maximum use rate of 20 ppm or 0.002 % (DDAC/DDABicarbonate)**
- **Volume is 42,000 gallons or 350,280 lbs**
- **Unit Exposures are based on CMA data for liquid pump and is 0.0075 mg a.i./lb (dermal)**
- **Body weight is 70 kg**
- **Calculation: Use rate (% a.i.) x Volume treated (lbs) x Unit exposures (mg a.i./lb) / Body weight (kg)**
- **MOE (dermal) is 16,000**

Paints- primary dermal and inhalation occupational

- **Maximum use rate of 0.05% (DDAC/DDABicarbonate)**
- **Volume is 1,000 gallons about 10,000 pounds**
- **Unit Exposures are based on CMA data for liquid pouring and are 140 ug a.i./lb (dermal) and 1.2 ug a.i./lb (inhalation)**
- **Body weight is 70 kg**
- **Calculation: Use rate (% a.i.) x Volume treated (lbs) x Unit exposures (ug a.i./lb) / Body weight (kg)**
- **MOE (dermal and inhalation) is 1,200 and >100,000**

Paints- secondary dermal and inhalation occupational

- **Maximum use rate of 0.05% (DDAC/DDABicarbonate)**
- **Volume is 5 gallons (50 lbs) for brush/roller applications and 50 gallons (500 pounds) for airless sprayer uses**
- **Unit Exposures are based on PHED data and are 38,000 ug a.i./lb (dermal, airless sprayer), 1.2 ug a.i./lb (inhalation, airless sprayer), 180,000 ug a.i./lb (dermal, brush/roller), and 1.2 ug a.i./lb (inhalation, brush/roller).**
- **Body weight is 70 kg**
- **Calculation: Use rate (% a.i.) x Volume treated (lbs) x Unit exposures (ug a.i./lb) / Body weight (kg)**
- **Brush/roller MOE (dermal and inhalation) is 187 and >100,000**
- **Airless sprayer MOE (dermal and inhalation) is 89 and >100,000**

Paints- secondary dermal and inhalation residential

- **Maximum use rate of 0.05% (DDAC/DDABicarbonate)**
- **Volume is 2 gallons (20 lbs) for brush/roller applications and 15 gallons (150 pounds) for airless sprayer uses**
- **Unit Exposures are based on PHED data and are 38,000 ug a.i./lb (dermal, airless sprayer), 1.2 ug a.i./lb (inhalation, airless sprayer), 180,000 ug a.i./lb (dermal, brush/roller), and 1.2 ug a.i./lb (inhalation, brush/roller).**
- **Body weight is 70 kg**
- **Calculation: Use rate (% a.i.) x Volume treated (lbs) x Unit exposures (ug a.i./lb) / Body weight (kg)**
- **Brush/roller MOE (dermal and inhalation) is 466 and >100,000**
- **Airless sprayer MOE (dermal and inhalation) is 300 and >100,000**

Aerosol Cans- primary handler dermal and inhalation occupational

- **Maximum use rate of 0.25% (DDAC/DDABicarbonate)**
- **Quantity 10,000 pounds**
- **Unit Exposures are based on CMA data for liquid pouring and are 140 ug a.i./lb (dermal) and 1.2 ug a.i./lb (inhalation)**

- **Body weight is 70 kg**
- **Calculation: Use rate (% a.i.) x Volume treated (lbs) x Unit exposures (ug a.i./lb) / Body weight (kg)**
- **MOE (dermal and inhalation) is 240 and 23,809**

Aerosol Cans- secondary handler dermal and inhalation occupational

- **Maximum use rate of 0.25% (DDAC/DDABicarbonate)**
- **Density of can 8 lbs/gal**
- **Volume of can 0.5 liters**
- **Unit Exposures are based on CMA data for both dermal and inhalation is 1960,560 ug a.i./lb**
- **Body weight is 70 kg**
- **Calculation: Use rate (% a.i.) x Density (lb/liters) x Volume (liters) x Unit exposures (ug a.i./lb) / Body weight (kg)**
- **MOE (dermal and inhalation) is 1,690 and 1,408**

Note: **Dermal endpoint for assessment used is 2 mg/kg/day. The registrant used a maximum application rate 0.25%; however product labels states that the application rate of** Carboserve **at a maximum application rate of 0.25%. This value includes the inerts and the max application rate should really only be of the active ingredient of 50% of 0.25% or 0.125%. The following represents the of differing values for unit exposures:**

- **Dermal: liquid pump of metal working fluid; CMA = 0.312 mg/lb a.i.**
- **Inhalation: Inhalation of metal working fluid; CMA = 0.00348 mg/lb a.i.**
- **Dermal: liquid pump of oil field uses; CMA = 0.00629 mg/lb a.i.**
- **Dermal and inhalation to liquid pumping of paints/aerosol cans; CMA = 0.135 and 0.00346 mg/lb a.i.**
- **PHED dermal and inhalation due to brush/roller: 24.0 and 0.280 mg/lb a.i.**
- **PHED dermal and inhalation due to brush/roller: 14.0 and 0.830 mg/lb a.i.**