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Exposure Assessment

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Dose: The Cornerstone of Toxicology

- All substances are poisons; there is none which is not a poison. The right ***dose*** differentiates a poison from a remedy.

  Paracelsus (1493-1541)

- Definition of Threshold
  - The ***dose*** below which a given effect is not observed.

Key Toxicology Definitions

- **Potential exposure** is the opportunity for contact with a chemical
- **Exposure** is contact with a chemical
- **Dose** is the amount actually taken into the body

Adapted from Casarett & Doull's *Toxicology: The Basic Science of Poisons*, 2001

(Klaassen, C.D., Ed) McGraw-Hill. New York

U.S. EPA: Exposure Does Not Equal Dose

- "The amount of a substance in the medium (air, diet, etc.) in which it is present or administered is the ***exposure*** concentration. The amount of the chemical that is received by the target, or the ***dose***, may be different from the exposure amount."

From: EPA. 1990. *Risk Assessment, Management and Communication of Drinking Water Contamination*. USEPA Office of Research and Development, Washington, D.C. EPA/625/4-89/024.

Dose: The Cornerstone of Causation

- PPM-years is the metric used by courts
  - Instantaneous measurement is ppm
  - Average over working day is 8 hour TWA
    - E.g, 1 ppm for 8 hours = 1.0 ppm TWA
  - Average of 8 hour TWA over year is ppm-years
    - E.g., 1 ppm TWA x 250 days = 1 ppm-year
- Cumulative exposure is total of all years over lifetime
    - E.g., 1 ppm-years for 5 years = 5 ppm-years

Dose: The Cornerstone of Causation

- "the relevant medical-scientific literature supports the conclusion that cumulative benzene exposure, at levels above 200 ppm years, can result in [AML]."

  Castellow v. Chevron USA, 97 F. Supp. 2d 780, 782 (S.D. Tex. 2000)

- consensus among scientists that a threshold of 100 ppm-years will cause leukemogenesis, scientists disagree over the effects of doses between 25 and 50 ppm-years

  Sutera v. The Perrier Group of America, Inc., 986 F. Supp. 655 (D. Mass. 1997)

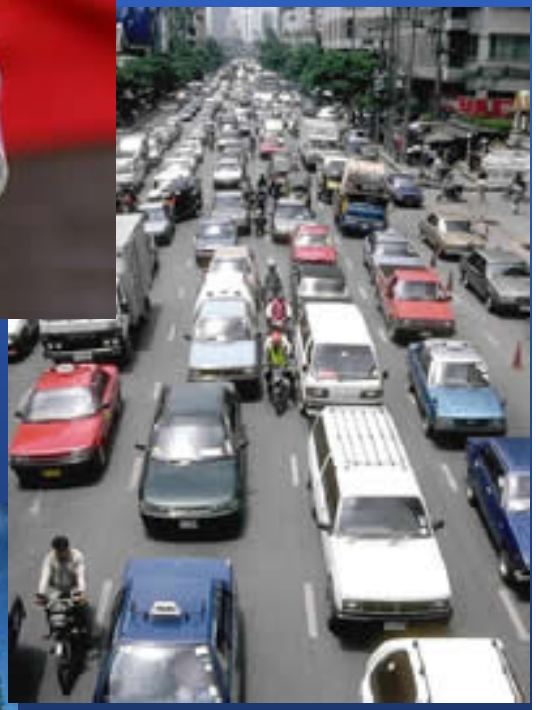
Benzene in Drinking Water

- Reported that Perrier bottled water was contaminated with low levels of benzene in excess of regulatory limits for drinking water
- Court rejected causation based on these low levels

Sutera v. The Perrier Group of America, Inc.
986 F. Supp. 655 (D. Mass. 1997)

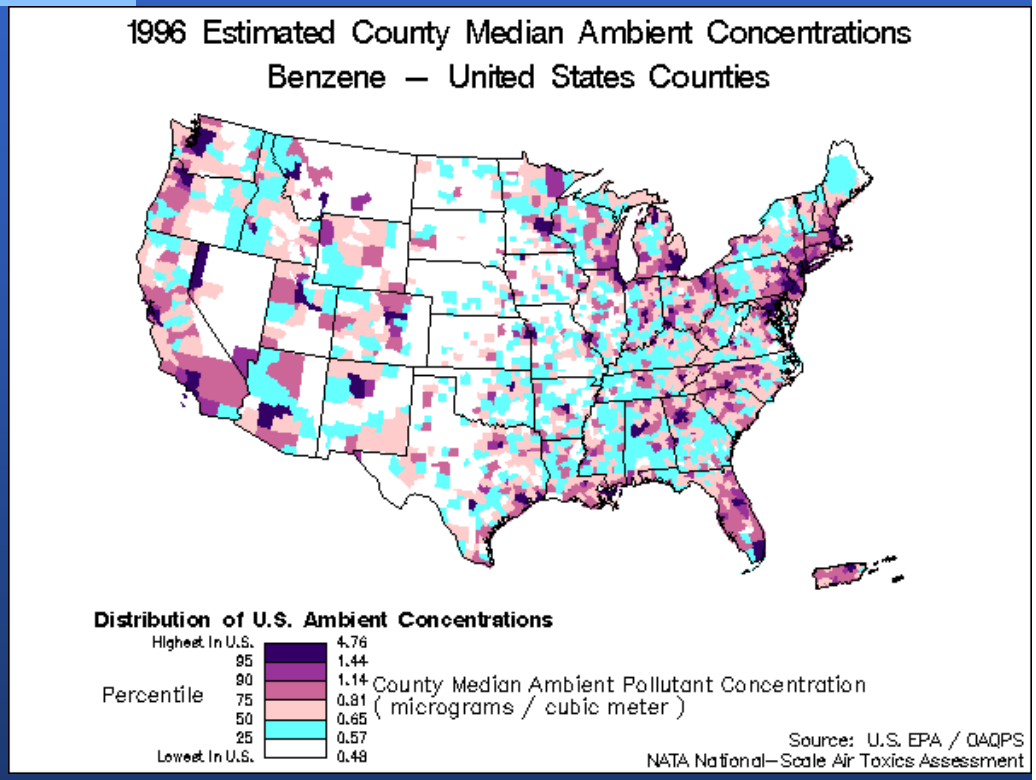
Benzene is Found Everywhere

- Industrial emissions
- Automotive exhaust
- Gasoline
- Cigarette smoke
- Household cleaners
- Drinking water
- Food
- Solvents



USA Human Exposure

- EPA– 1996 Estimated Median Exposure Concentration of Benzene in the United States

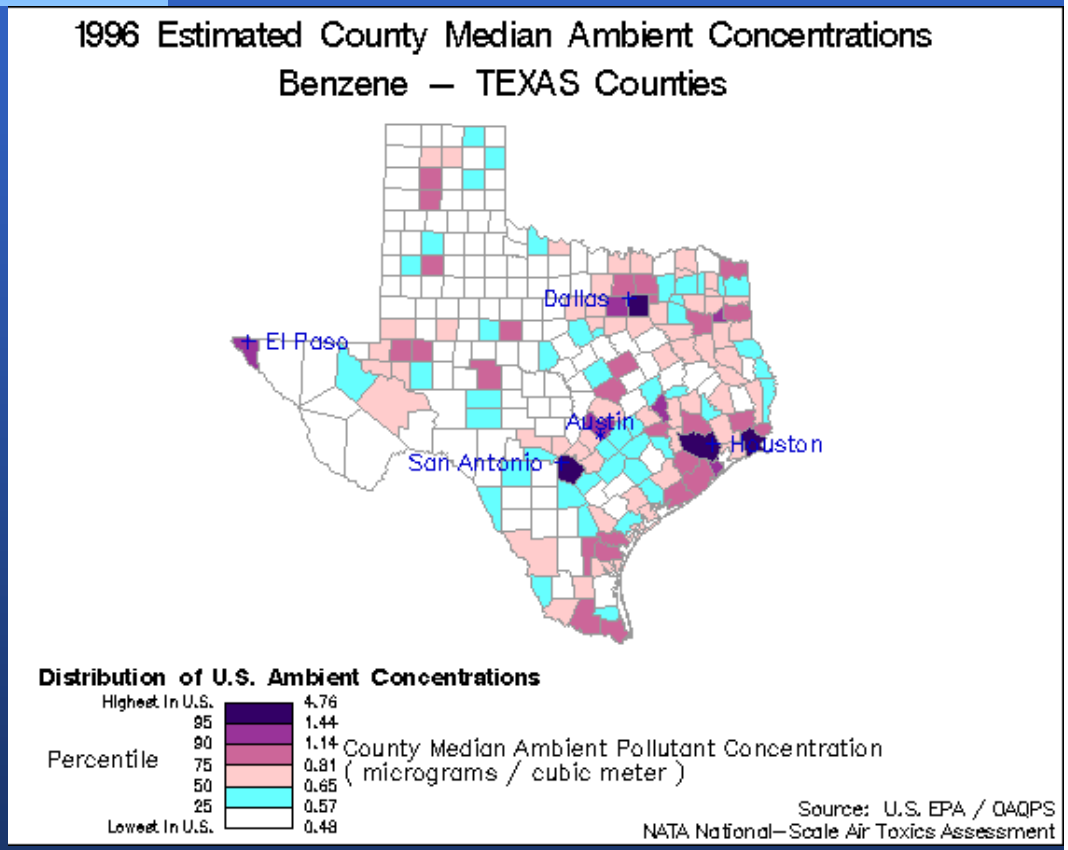


Source: US EPA/QAQPS

NATA National–Scale Air Toxics Assessment

Texas Human Exposure

- EPA Region 6 –1996 Estimated Median Exposure Concentration of Benzene in Texas
- San Antonio, Houston, Dallas are in the 95th Percentile for Ambient Air Benzene Exposure



Source: US EPA/QAQPS

NATA National–Scale Air Toxics Assessment

Texas Law on Exposure Assessment

Merrell-Dow Pharmaceuticals v. Havner

Requirements to Establish Causation

- Statistically significant doubling of the risk
- Multiple studies among different groups
- Proof injured person was exposed to the same substance
- Exposure or dose levels were equal to or greater than in studies
- Exposure occurred before onset of injury
- Timing of onset of injury consistent with those in the studies

953 S.W.2d 706 (Tex. 1997)

Frias v. Atlantic Richfield

Requires specific exposure assessment

- Scientifically reliable evidence of level and period of exposure necessary to cause the disease
- Legally sufficient evidence plaintiff was exposed at that level for that period

104 S.W.3d 925 (Tex. App.–Hous. [14th Dist.] 2003, no writ)

Frias v. Atlantic Richfield

- Abstract and indefinite exposure assessment legally insufficient:
  - "'frequent contact' with and 'regular use' of benzene containing products, 'significant vapor hazard,' and 'dangerously high' levels of benzene"
  - "*consistently exposed* to benzene levels in the 10 to 20 ppm range … and that he had *regular exposures* above 100 ppm … . *Occasional* peak exposures of hundreds of ppm and, in some cases, approaching 1000 ppm"
- "such indefinite terms as 'consistently,' 'regular,' and 'occasional' leave the frequency (*i.e.*, hourly, daily, weekly, monthly, etc.) and duration (minutes, hours) of exposure, at any single exposure level and in total, subject to wide variance and thus largely open to speculation"

104 S.W.3d 925 (Tex. App.–Hous. [14th Dist.] 2003, no writ)

Castellow v. Chevron USA

- Relevant Literature Establishes Exposure for Causation
  - Exposure above 200 ppm-years can cause AML
- Industrial Hygienist Assessment Unreliable
  - Kept revising assessment from 177 to 104 to 61 ppm years
  - One assessment of benzene exposure could only occur from potentially lethal gasoline exposure twice daily for 10 years
  - Assessment made on assumptions unsupported in the record
- Unreliable assessment leads to speculative causal link

97 F.Supp.2d 780 (S. D. Tex. 2000)

Types of Exposure Assessments

Empirical Assessment

Physical Symptomology

- Odors in the workplace
- Dizziness and Lightheadedness
- Nausea
- Headaches
- Watery Eyes
- Cracked or Dry Skin
- Odors on body, clothing, and breath

Empirical Assessment

Inaccuracies in Assessment by Odor Thresholds

- Multiple substances typically found in work place
- Difficult to discriminate and distinguish odors
- Workers not trained to recognize specific odors
- Misconceptions and erroneous information on odors
- Odor threshold subject to large individual variation
- Odor threshold subject to desensitization

Empirical Assessment

Odor Thresholds

- Based on Published Odor Thresholds
- Need to know percentage of benzene content
- Example – Based on Odor of Gasoline
  - Odor threshold for gasoline is 140 ppm
  - Benzene content of gasoline is 1%
  - Benzene exposure is approx. 1.4 ppm (1% of 140 ppm)

Deposition of Peter Infante, January 10, 2005

Actual Assessment

Industrial Hygiene Monitoring Data

- Most accurate form of assessment
- Based upon monitoring of actual conditions
- Exposure is recorded and maintained

Sample Monitoring Data

ABC OIL COMPANY

PERSONNEL MONITORING FOR BENZENE EXPOSURE

Employee Monitored: Mick Jagger SSN: 123-32-1000

Date: 12-2-95

Project & Company: Spoes

Area of Monitoring: Operator

Sub-Area (if applicable):

Type of Monitoring --- (PERSONAL) --- TASK --- CEILING ---

OTHER:

TIME STARTED: 8 Am TIME STOPPED: 4 pm

PPM Benzene: 0.1 TWA

PPM Benzene: Peak Concentration

Respirator Used: No Type:

ABC OIL COMPANY

PERSONNEL MONITORING FOR BENZENE EXPOSURE

Employee Monitored: Mick Jagger SSN: 123-32-1000

Date: 12-3-95

Project & Company: Spoes

Area of Monitoring: Operator

Sub-Area (if applicable):

Type of Monitoring --- (PERSONAL) --- TASK --- CEILING ---

OTHER:

TIME STARTED: 12 pm TIME STOPPED: 2 pm

PPM Benzene: 3.0 TWA

PPM Benzene: 6.5 Peak Concentration

Respirator Used: Yes Type: C

Literature Review

Reported Industrial Hygiene Monitoring Results

- Used when there is no actual or empirical data
- Only reliable if conditions are similar
- Many Pitfalls
  - Specific products usually not identified
  - Benzene content not identified
  - Ventilation characteristics not identified
  - Many from foreign countries with poor industrial hygiene programs

Literature Review

Literature reporting benzene exposure levels

- Caldwell, et al, Hydrocarbon Solvent Exposure Data: Compilation and Analysis of the Literature, AIHAJ 61:881-894 (2000)
- Nelson, et al, Historical Characterization of Exposure to Mixed Solvents for an Epidemiologic Study of Automotive Assembly Plant Workers, Appl. Occup. Environ. Hyg. 8(8):693-702 (1993)
- Winder and Turner, Solvent Exposure and Related Work Practices Amongst Apprentice Spray Painters in Automotive Body Repair Workshops, Ann. Occ. Hyg., 36:385-394 (1992)

Literature Review

Literature reporting benzene exposure levels (cont)

- Chen, et al, Exposure to mixtures of solvents among paint workers and biochemical alterations of liver function, Br. J. Indus. Med., 48:696-701 (1991)
- Medinilla and Espigares, Contamination by Organic Solvents in Auto Paint Shops, Ann. Occ. Hyg., 32:509-513 (1988)
- Jayjock and Levin, Health Hazards in a Small Automotive Body Repair Shop, Ann. Occ. Hyg., 28:19-29 (1984)
- Wallace, Major Sources of Benzene Exposure, Env. Health Persp., 82:165-169 (1989)

Literature Review

Literature reporting benzene exposure levels (cont)

- New Hampshire Auto Dealers Association, Worker Exposure to Volatile Aliphatic and Aromatic Hydrocarbons in Eight Auto body paint shops in New Hampshire, 1987
- NIOSH Health Hazard Evaluation Report: HETA #2002-0418-2912, Richards Industries, Cincinnati, Ohio, September 2003
- NIOSH Health Hazard Evaluation Report: HETA 91-0341-2380, Bryan Custom Plastics, Bryan, Ohio, January 1994
- OSHA Inspection Number 102475225, Superior Auto Body, Inc., Eau Claire, Wisconsin, October 1991

Literature Review

Literature reporting benzene exposure levels (cont)

- New Hampshire Auto Dealers Association–1987
  - P. 1–"On May 22, 1987, Environmental Control Technologies completed an assessment of worker exposure to volatile aliphatic and aromatic organic compounds evolving from paints and varnishes used in auto body paint shops. Samples of workroom atmospheres were collected from eight auto body paint shops during February 1987."
  - P. 2–"None of the auto paint shop atmospheres examined in this study show any evidence of benzene or methylene chloride contamination."
  - P. 5–"…worker exposure to volatile aliphatic and aromatic compounds are well below current OSHA threshold limit values."

Governmental Investigation

OSHA examined benzene in its regulatory process

- Preamble to 1987 Benzene Standard
  - Record evidence indicates that liquid mixtures with less than 0.1 percent benzene are unlikely to cause exposures through dermal absorption and inhalation equivalent to the amount inhaled at the action level. [The "action level" was an eight hour time weighted average airborne concentration of 0.5 ppm. 29 C.F.R. § 1910.1028(a)(3)(b).]

Federal Register: Occupational Exposure to Benzene, Final Rule, 52 F.R. 34460, 34461 (September 11, 1987)

Exposure Modeling
Well Mixed Room Model

Industrial Hygiene Investigation

Identify All Relevant Data

- Identify potential locations of exposure
  - Site inspection, if possible
  - Testimony of plaintiff and/or witnesses
- Prepare layout of facility
  - Dimensions, including walls, doors, windows, vents, exhaust
  - Location of paint booth, including exhaust

Industrial Hygiene Investigation

- Identify tasks performed
  - Layout all steps, where performed and time to perform
  - Identify products and equipment used (including clean-up)
  - Identify personal protective equipment (respirator, gloves, clothing)
- Identify All Products Used at the Facility
  - Manufacturer, name, type, size, amount, labels, MSDS, years of use
- Identify Where Products Stored at Facility
  - Where stored (e.g. paint room, open floor, etc.)
  - How stored (e.g. open barrels, closed containers, etc.)

Industrial Hygiene Investigation

- Identify All Products Used at the Facility
  - Manufacturer, name, type, size, amount, labels, MSDS, years of use
- Identify Where Products Stored at Facility
  - Where stored (e.g. paint room, open floor, etc.)
  - How stored (e.g. open barrels, closed containers, etc.)
- Respiratory Protection
    - Types (e.g. cartridge, air-supplied, paper) and storage (e.g sealed bag, open air)
    - How often used, how often filters changed
    - Training and fit testing
    - Did plaintiff have facial hair
    - Did plaintiff ever smell the substance with respirator in use

Industrial Hygiene Investigation

- Ventilation
  - Exhaust fans (types, size, air flow volume, external exhaust)
  - How often running (e.g. continuous, intermittent, seasonal)
  - Size and location of doors and windows and how often open
- Industrial hygiene monitoring results, if any
- Did plaintiff ever experience adverse health effects
  - Dizziness, nausea, watery eyes, burning or cracking skin, etc.

Industrial Hygiene Investigation

- Plaintiff physical appearance after work/ at lunch
  - Paint on skin (e.g. face around respirator fit, arms, hands, etc.)
  - Work place odors on clothes, hair, body, breath
  - Rough/red/cracked skin as evidence of dermal exposure
- Employment related medical records
  - Medical surveillance, blood testing, exposure results
  - Respiratory protection

Sample Task Analysis

Task	Frequency	Duration	Potential Exposure	Exposure Control Available
Overall paint				
mix paint				wore respirator (CC) to mix for overall
paint	mostly SS (BB): 2-3 cars/wk (AA): EE - 90% of time (AA) Ave 4 cars/wk (AA); Ave 3-4 cars/wk (BB); 75% SS, 25% (EE, BB); CC did majority of painting 81-82 (AA); EE did 10% of overall (AA); could do 6-7/wk or none (BB)	40 min for 2 coats (CC); ≈ 1 hour (CC); ≈ 1 hour (BB); 1-2 hours (DD); 2-3 coats of paint ( )	4-6 quarts/car (CC); 1 gallon/car (BB); acrylic enamel to 1990's-base coat/clear coat after (BB)	done in booth (AA); spray booth exhaust ventilation (CC); paint mist lingers in air ≈ 3 minutes after painting stops (CC?) coveralls (DD); paint suit w/hood (CC); no gloves or goggles (CC, BB, DD); used supplied air respirator 80% of the time (CC); did not wear respirator (BB); no gloves (BB); charcoal respirator (CC); filters changed when smelled paint (BB); filters for cartridge resp were supposed to be kept sealed when not in use - but were not (BB); did not wear respirator in own shop (BB); paint would seep around bridge of respirator (BB); painter wore freshair paint suit or charcoal respirator (DD); FF wore resp for full paint job (DD); FF had a beard - on & off (BB, DD); wore safety equipment recommended by paint manuf (CC); dizzy after painting (CC); thinner burned hands (CC); In his own shop "wore mask, hood-type thing, and thing that covered his head" (FF); wore gloves (FF); paint on face but not on hands (FF)

Model Assumptions

	Big Booth	Booth
Size of booth	10' x 30' x 10' 6" (5670 cu ft) (160 m^3)	15' 3" x 29' 2" x 8' 4" (3480 cu ft) (104.7 m^3)
Booth type	modified side draft	side draft
Exhaust Air	1558 CFM (44.12 m^3/min)	Fan not operable (disconnected). Fan looked like compressor fan motor from air conditioner. Assume ½ of Floyd's booth (780 cfm or 22.09 m^3/min).
Intake Air	Intake air entered the booth perpendicular to the air flow. Three 16.5" x 16.5" square holes in the wall (with filters) on the two long sides of the booth. Placement such that intake closest to the rolltop door was located approximately 3/4 the lenght of the booth away from the exhaust fan. Many fugitive intakes in perimeter of overhead doors.	No discrete opening for intake air. Booth was converted garage. Roll top door assumed to be partially open to provide make-up air. However, vent above the roll top door may have been used as well, but install date was not clear.
Paint/Solvent Usage	4-6 quarts per 40-60 minutes for 2 coats; usually 2-3 quarts per 20-30 minutes with 10 minutes between coats to flash; also wipe coat prior to painting (est. 1 pt per car taking less than 10 minutes)	4-6 quarts per 40-60 minutes for 2 coats; usually 2-3 quarts per 20-30 minutes with 10 minutes between coats to flash; also wipe coat prior to painting (est. 1 pt per car taking less than 10 minutes)
Trace benzene (w/w %)	Paint (automotive) - .009%; diluent solvents - 3602 (.001%), Thin1(.027%), Thin2(.009%), 3696 (.006%), wipe coat - Wipe solvent (.009%); Calculation based on 1:1 ratio of auto paint used to thin.	Paint (automotive) - .009%; diluent solvents - 3602 (.001%), Thin1(.027%), Thin2(.009%), 3696 (.006%), wipe coat - Wipe solvent (.009%); Calculation based on 1:1 ratio of auto paint used to thin.
Mixing paints	mixing area adjacent to exhaust fan - 5-10 min	mixing area adjacent to exhaust fan - 5-10 min
Equipment clean-up	solvent in cup - spray into exhaust fan or spray outside - 5-10 min	solvent in cup - spray into exhaust fan or spray outside - 5-10 min
Personal clean-up	5-10 minutes	5-10 minutes
Personal Protective Equipment (PPE)	air supplied respirator - 80% of the time; 1/2 mask other times; no gloves	1/2 mask respirator; gloves

Model Results

		Big Booth		Booth
Well Mixed Room Model - Constant Contaminant Emission Rate				
Painting	Generation rate (G) =	15.31 mg/min	Generation rate (G) =	15.31 mg/min
	Air volume (Q) =	44.12 m^3/min	Air volume (Q) =	22.09 m^3/min
	Room Volume (V) =	160.6 m^3	Room Volume (V) =	98.54 m^3
	Concentration (C) =	.11 ppm	Concentration (C) =	.21 ppm
	Exposure Time =	30 min	Exposure Time =	30 min
Wipe coat	Generation rate (G) =	3.55 mg/min	Generation rate (G) =	3.55 mg/min
	Concentration =	.02 ppm	Concentration =	.04 ppm
	Exposure Time =	10 min	Exposure Time =	10 min
Painting (20 min)	Generation rate (G) =	22.96 mg/min	Generation rate (G) =	22.96 mg/min
	Air volume (Q) =	44.12 m^3/min	Air volume (Q) =	22.09 m^3/min
	Room Volume (V) =	160.6 m^3	Room Volume (V) =	98.54 m^3
	Concentration (C) =	.16 ppm	Concentration (C) =	.31 ppm
Wipe coat	Generation rate (G) =	3.55 mg/min	Generation rate (G) =	3.55 mg/min
	Concentration =	.02 ppm	Concentration =	.04 ppm
	Exposure Time =	10 min	Exposure Time =	10 min

Model Results

Using the Well Mixed Room Model to calculate the TWA at Shop for wipe coat (10 min) and two coats (30 min each) yields the following:

((.02 ppm) (10 min) + (.11 ppm) (30 min) + (.11 ppm) (30 min))/70 = 6.82/70 = .097 ppm

To calculate an 8-hour TWA, a concentration equivalent to 25% of the calculated value (.097 ppm) was used to estimate exposure due to paint mixing and equipment clean-up (15 min). It was assumed there was zero (0) exposure for the remaining period.

((.024 ppm) (15 min) + (.097 ppm) (70 min))/480 = .015 ppm

Using the Well Mixed Room Model to calculate the TWA at Shop # 2 /Booth for wipe coat (10 min) and two coats (30 min each) = 70 minutes yields the following:

((.04 ppm) (10 min) + (.21 ppm) (30 min) + (.21 ppm) (30 min))/70 = .185 ppm

To calculate an 8-hour TWA, a concentration equivalent to 25% of the calculated value (.185 ppm) was used to estimate exposure due to paint mixing and equipment clean-up (15 min). It was assumed there was zero (0) exposure for the remaining period.

((.046 ppm) (15 min) + (.185 ppm) (70 min))/480 = .028 ppm

Bernardo Ramazzini

Father of Industrial Hygiene
And Exposure Assessment