Navigating the AHFA Prop 65 Workbook

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California Proposition 65

- The State of California publishes a list of approximately 900 chemicals that are known to cause cancer or birth defects or other reproductive harm
- Prop 65 requires businesses to notify Californians about significant amounts of these chemicals in the products they purchase so that they can make informed decisions about protecting themselves from exposure to these chemicals
- Businesses are required to provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical
- **Businesses are exempt from the warning requirement if the exposures they cause are so low as to create no significant risk of cancer or birth defects or other reproductive harm**

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Safe Harbor Numbers

- The Office of Environmental Health Hazard Assessment (OEHHA) develops numerical guidance levels, known as “safe harbor levels” for determining whether a warning is necessary
- Safe harbor levels consist of No Significant Risk Levels for chemicals listed as causing cancer or Maximum Allowable Dose Levels for chemicals listed as causing birth defects or other reproductive harm
- Safe harbor levels are express on a µg/day basis and represent ‘acceptable’ daily exposure levels to the listed chemicals
- Safe harbor levels are available for over 300 chemicals; of the eight (8) pilot chemicals, only MIBK does not have a safe harbor level
- OEHHA has adopted regulations that provide guidance for calculating a safe harbor level in the absence of one

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Prop 65 Evaluation

- Businesses subject to Proposition 65 are required to provide a warning if they cause **exposures** to:
  i. chemicals listed as causing cancer at levels that exceed the ‘no significant risk level’; or,
  ii. chemicals listed as causing birth defects or reproductive harm that exceed 1/1000th of the “no observable effect level.”
- By law, a warning must be given for listed chemicals unless exposure is low enough to pose no significant risk of cancer or is significantly below levels observed to cause birth defects or other reproductive harm
- **A business has "safe harbor" from Proposition 65 warning requirements if exposure to a chemical occurs at or below the safe harbor levels**

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AHFA and Prop 65

- A business can combine known information about how consumers use their product and how they might be exposed to a listed chemical
- For example, when looking at the four AHFA product categories (wood casegoods, upholstered fabric, upholstered leather, plastic/metal), exposure can result through one of three pathways, depending on the chemical of concern:
  - Oral (ingestion of dust containing non-volatile chemicals; hand to mouth contact following direct dermal contact)
  - Inhalation (of dusts and/or volatile chemicals following off-gassing)
  - Dermal (direct contact with various constituent of the furniture; including fabric/leather/faux leather surfaces, plastic/rubber arm rests, other hard surfaces)

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Exposure-Based Limits

- Proposition 65 Limits (NSRL/MADL are exposure-based), expressed as µg/day, and do not allow for a direct comparison to total or bulk chemical (ppm) analysis
- Every evaluation/assessment is product specific
- Total or bulk chemical (ppm) analysis can be used to conduct an exposure/risk assessment that will help with your decision making process regarding the need to warning labels and/or reformulation
- Specialized testing can help to lessen uncertainties and provide more realistic exposure estimates
  - Bioavailable/bioaccessible/leachable amount of chemical
  - Simulated sweat/saliva extraction
  - Wipe testing
  - Chamber test

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Comparing test results to the list

- Analytical results reported as ppm (µg/g or mg/g), µg/m^2 (surface area) or µg/m^3 (air concentration)
- Prop 65 list (NSRL and MADL) is µg/day
- µg/day ≠ ppm
- Not every chemical has an NSRL/MADL
  - Common question: OEHHA doesn't provide an MADL/NSRL, so I'm ok, right?
  - No…..
  - Examples
    - BPA – dermal number provided, what about oral (hand-to-mouth) exposure?
    - PFOA/PFOS – listed November 10, 2017
  - Develop *de novo* (can be difficult/expensive)
  - Literature value (i.e. BPA oral)
  - Another regulatory agency (EPA, Health Canada, ECHA)

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The Workbooks

- TAB 1 – The List of Lists
- TAB 2 – Formaldehyde
- TAB 3 – Metals
- TAB 4 – Organics

TAB 1 – The List of Lists

- The Proposition 65 list of chemicals contains more than 900 chemicals known by the state of California to cause cancer or reproductive toxicity
- The list is dynamic and always changing (latest version is dated 29-Dec-17)
- Given the size of the list, it is not possible or necessary for American Home Furnishings Alliance (AHFA) members to screen their products against the entire list
- TAB 1 helps to prioritize and consolidate the list

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Prioritization Process

- The prioritization process involved toxicological, analytical and legal advisors as well as a subset of AHFA members knowledgeable about chemicals used in the manufacturing process
- The goal was to consider the full list of 900 chemicals and come up with a subset of chemicals for priority evaluation
- Design testing strategy based on your product
  - Nature of the product
  - Product formulation
  - ‘target chemicals’ and ‘target products’

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Initial screening

- 590 chemicals on the Prop 65 list were definitively identified as not being used in the manufacture of furniture and not likely present in finished furniture products
- 69 chemicals were determined to be definitely present within furniture and requiring further consideration
- 189 chemicals were tagged as possibly being found in furniture products but at low levels and with a limited level of concern

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69 Listed Chemical in Furniture

- Further prioritization necessary
  - Availability of information (toxicology, consent judgements)
    - Does a No Significant Risk Level (NSRL)/Maximum Allowable Dose Level (MADL) exist for the chemical
    - Do other reputable regulatory agencies have a toxicity reference value (TRV) for the chemical
    - Are there multiple consent judgments which provide consistent warning trigger standards for the Listed Chemical (i.e., phthalates – 1000 ppm)?
  - Enforcement history/Potential for plaintiff action
    - Has the chemical been subject of past enforcement actions
    - Is it an easy target because it is easy to detect or widely known to exist?
    - Has there been mainstream media scrutiny raising “alarms” about the Listed Chemical?
    - Is the Listed Chemical already disclosed on labels or in other materials?
  - Specific Listed Chemical exposure assessment information.
    - Has a screening level been established (by OEHHA, through consent judgments or by other respected public health authorities)?
    - Can a screening level be readily established based on simplified or streamlined exposure assessments?
    - Are actual chemical levels in final products known or readily ascertainable?
    - Is this information in a form that can be used for the purposes of Proposition 65?

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Further prioritization continued

- Accessibility of the Listed Chemical; what is the likelihood of consumer exposure due to location or use in furniture? Is the Listed Chemical in:
    - Surface coatings
    - Fabrics
    - Wood frame/wood product
    - Minor components or constituents
    - Inaccessible chemical or component due to cover or location
  - Plausibility of average user exposures (aka “reasonable use scenarios”)
    - Inhalation of gaseous compounds
    - Rate of release of gaseous compounds (immediate or slow over time)
    - Dermal contact
    - Oral exposure (hand-to-mouth, mouthing by small children)

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Further Prioritization

- Class D - Low Priority
  - 21 were categorized as LP or Low Priority based on their current use in furniture products and the likelihood of enforcement by professional plaintiffs
  - No further action at this time
- Class A – Existing Screening Criteria
  - 9 were categorized as Class A only
  - Chemical content based on existing information
    - Based on the product ingredient list containing chemicals name, CAS registry number and % by weight chemical content
  - Look up tables based on established benchmarks
    - Other regulatory regimes (CPSC, CARB)
    - Consent judgements
    - Safe Use Determinations
- Class B – Streamlined Risk Assessment
  - 23 were categorized as Class A/B
  - If necessary, risk assessment can be conducted for any of these 23 Class A/B chemicals
- Class C – Detailed Risk Assessment (high priority)
  - 10 were categorized as Class A/B/C (high priority)

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High Priority Chemicals

- Formaldehyde
- Other Organics
  - Benzene
  - Dichloromethane
  - Methanol
  - MIBK
  - Toluene
- Metals
  - Chromium (hexavalent compounds)
  - Lead and compounds
- Halogenated Flame Retardants
  - Tris(1,3-dichloro-2-propyl) phosphate (TDCPP)
  - Tris(2,3-dibromopropyl)phosphate
  - Tris(2-chloroethyl) phosphate

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Other Potential Concerns

- Styrene
- BPA
- Phthalates
- PFOS/PFOA

Next Steps

- If your product contains a listed/priority substance, you have three options:
  - Warning label
  - Reformulate
  - Safe Harbor Assessment

  …. Workbook TABs 2, 3 and 4

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TABs 2, 3 and 4 – the Safe Harbor Assessment

- A business can combine known information about how consumers use their product and how they might be exposed to a listed chemical
- The SHA provides a scientific evaluation of exposure and risk and can provide some insight into a particular product
- The evaluation should adhere to the California Environmental Protection Agency (Cal/EPA)'s Office of Environmental Health Hazard Assessment (OEHHA) guidance where available:
  - The evaluation can follow the Safety Use Determination (SUD) process established by OEHHA
  - Interpretive Guidelines such as Guideline for Hand-to-Mouth Transfer of Lead through Exposure to Consumer Products
  - Risk Assessment Guidance
- US EPA guidance is also helpful
  - Risk Assessment Guidance for Superfund (RAGS)
  - Exposure Factors Handbook
- Other Sources can be informative
  - Scientific literature
  - Other regulatory jurisdictions

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What should be considered in the SHA

- Chemical content (ppm)
- Bioavailable/accessible chemical amount (µg/g, µg/m^2, µg/m^3)
- Product characteristics/use characteristics
  - e.g., one time installation, daily contact, intermittent use
- Pathways of exposure
  - Dermal (direct contact)
  - Oral (direct ingestion and hand-to-mouth)
  - Inhalation (for volatile chemicals and airborne dusts)
- Types of Users (Receptors)
  - Commercial
  - Consumer
    - Adult
    - Child

The SHA Exposure Model

- An exposure model is developed to estimate how the receptor (a person) interacts with the product and how the receptor is exposed to the chemical(s) in the product:
  - Characteristics of the receptor
    - Professional vs. consumer
    - Age, body weight, dermal contact surface, HTM characteristics, breathing rate, etc.
  - Characteristics of the product and its use
    - Size, weight and chemical content
    - How often is the product used/contacted by the user
    - How long is the product used (daily interaction and product lifetime)
  - Chemical characteristics
    - Volatility
    - Migration (availability)
    - Absorption coefficients (dermal/oral)
    - Toxicity (MADL/NSRL)

The Workbooks

- The workbooks were designed to develop a simplified SHA model for specific chemicals (formaldehyde, metals, organics) and product types (furniture)
- The workbook approach was selected so that the SHA model could be applied by the user to specific pieces of furniture and use scenarios
  - desk vs. table vs. hutch etc.
  - child intended vs. all purpose

TAB 2 – Formaldehyde

- Formaldehyde is present in furniture as a component of composite wood
- Formaldehyde is also used in fiberglass acoustic insulation, glues, fabrics, paints and coatings, lacquers and finishes, and paper products, all commonly used to produce home furnishings
- Formaldehyde is a gas that is released from products to indoor air through a process commonly known as off-gassing
- Formaldehyde (gas) is listed in Prop. 65 as a chemical know to the State to cause cancer
- The workbook is designed to assist furniture manufacturers predict or determine the rate at which formaldehyde will be released from their products, thereby allowing manufacturers to determine if labelling for the purposes of Prop. 65 is necessary
- In addition to generic examples, the workbook provides a framework to use product specific data and assumptions that will allow for product specific evaluations and determinations

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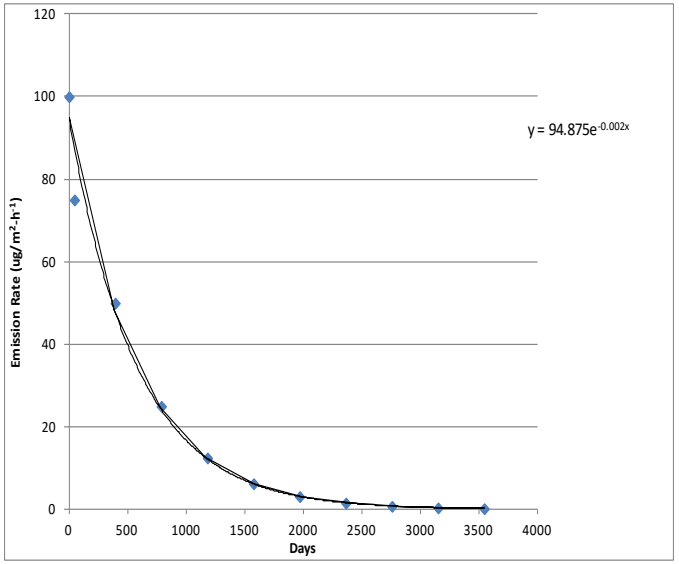
Formaldehyde Emissions from Furniture

- Formaldehyde is emitted from products over the lifetime of the product
- The amount of formaldehyde released is known to diminish over time; this process is know as decay
- The decay curve can be used along with predicted or measured emission rates to predict long-term exposure of people to formaldehyde
- Due to decay, formaldehyde emissions and exposures decrease dramatically over time; this trend can be considered within the framework of Prop. 65



- **The workbook allows for the prediction of exposure for intact furniture pieces; it is also scalable to estimate exposure from smaller parts**
- **Prop 65 does not necessarily require the consideration of furniture sets when individual pieces are sold separately; legal advice should be sought on this issue**
- **These long-term exposure estimates can be compared to the NSRL (no significant risk level) provided by the State to determine if labelling for the purposes of Prop. 65 is required**

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Formaldehyde – Safe Harbor Assessment

- The NSRL for Formaldehyde (air) is 40 µg/day (equivalent to an average air concentration of 2.67 µg/m^3)
  - Inhalation is the only viable pathway for formaldehyde
  - Primary source of formaldehyde in furniture is composite wood although residual levels can also be present in adhesives, paints and coatings
- A standard test method designed to determine VOC (including formaldehyde) emissions from products such as the ANSI/BIFMA M7.1-2011 test method (a chamber test designed to determine emission factors, which represent the rate at which a VOC is emitted from a product normalized to the surface area of the product) provides the best type of information to conduct the Safe Harbor Assessment.
- The results of the chamber test (expressed as µg/m^2-h) can be used to estimate exposure in a manner that can be compared to the NSRL

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Safe Harbor Assessment - assumptions

- To estimate exposure, the SHA requires exposure assumptions
  - Receptor
    - Breathing rate
    - Exposure frequency
    - Exposure duration
  - Product
    - Product lifetime (note OEHHA has indicated that someone could purchase an identical replacement product after the usable lifetime of a product)
  - Residential
    - Air exchange rates
    - Room/house size

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‘Acceptable’ Emission Rates

Wood Product Surface Area (m^2)	***Initial ‘Acceptable’ Emission Factor ($\mu g/h^{-1}$)***	***Average Daily ‘Acceptable’ Emission Factor over a 10-Year Duration ($\mu g/h^{-1}$)***
Full product/set (independent of surface area)	2000	260
Wood Product Surface Area (m^2)	***Initial ‘Acceptable’ Emission Factor ($\mu g/m^2\ h^{-1}$)***	***Average Daily ‘Acceptable’ Emission Factor over a 10-Year Duration ($\mu g/m^2\ h^{-1}$)***
0.5	4000	520
1	2000	260
10	200	26
25	80	10
50	40	5

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Example Calculation – Company X Furniture Set[a]			
Parameter	Default (acceptable)	Chamber Results for Company X – Assuming 10 Year Product Lifespan	Chamber Results for Company X – Assuming 20 Year Product Lifespan
Receptor breathing rate (m^3/day)	20	20	20
Exposure frequency (hours/day)	24	24	24
Hours per Day	24	24	24
Exposure frequency (days/year)	350	350	350
Days per Year	365	365	365
Exposure duration (years)	70	70	70
Lifetime (averaging time) (years)	70	70	70
Product Lifespan (years)	10	10	20
Initial Product Emission Rate (µg/hr)	2000	1527[b]	1527[b]
Initial Exposure Concentration (µg/m^3)	9.2	12.5[b]	12.5[b]
Average Exposure Concentration (µg/m^3)	1.2	1.6[c]	0.83[c]
Average Daily Exposure (µg/day)	40	31[c]	16[c]

[a] Company X Furniture Set is comprised of multiple pieces; Prop 65 may or may not require consideration of the set if the items are sold separately, rather it may be sufficient to consider each individual piece as a stand-alone piece if it is plausible that each piece could be sold alone. Legal advice should be sought when determining whether to evaluate a single component or a set of furniture.

[b] Values are based on emission rates estimated through product chamber tests and the application of a default ventilation rate of 122 m^3/h.

[c] Values are based on product chamber tests and theoretical emission decay curves.

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CARB Phase 2 vs Prop 65

- The TAB 2 workbook was used to compare four (4) dressers made from 8 m^2 (86 sq ft) of CARB Phase 2 compliant composite wood

Example Calculation – CARB Phase 2 Compliant Dresser				
Composite Wood Material	CARB-Compliant Emission Factor ($\mu g/m^2\ h^{-1}$)	Surface area of product (m^2)	Safe Initial Emission Factor ($\mu g/m^2\ h^{-1}$)	Need to Label?
Plywood	32	8.0	250	No
Particleboard	128	8.0	250	No
MDF	260	8.0	250	Yes
Thin MDF	307	8.0	250	Yes

- The workbook indicates that a dresser made entirely from CARB Phase 2 compliant plywood or particleboard would not require labelling for the purposes of Prop. 65; however, the same dressers made from CARB Phase 2 compliant MDF or thin MDF may require labelling
- Alternatively, further product testing (large chamber test with the intact dresser following a methodology such as ANSI/BIFMA M7.1-2011 or ASTM E1333-96) will provide product specific emission factors that can be used to refine the assumptions for a particular piece of furniture
- Based on a limited data set, it would appear that the results of a product specific chamber test will provide emission factors substantially less than those predicted based on the characteristics of CARB Phase 2 compliant wood material

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TAB 3 - Metals

- Arsenic
- Cadmium
- Hexavalent chromium
- Lead
- Nickel

- NOTE: although not Class C, arsenic, cadmium and nickel were included in the workbook due to their similarity to other priority compounds

Metals in Furniture

- Metal furniture
- Hardware (nails, screws, staples, handles, knobs, brackets and hinges)
- Fabrics (including leather), paints, dyes, and finishes
- Natural components of wood
- Pressure treated wood

Testing for Metals

- Total metal analysis
  - ICP
  - XRF
- Available metals
  - Wipe sampling (for hard surfaces)
  - Simulated sweat extract (for hard or soft surfaces)

Notes:

- Ensure adequate detection limits
- Wipe sampling is only necessary on products/surfaces known to contain metals

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Metals – NSRL/MADL

Summary of Safe Harbor Levels (µg/day)		
Chemical	NSRL	MADL
Arsenic (inorganic arsenic compounds)	0.06 (inhalation) 10 (except inhalation)	Listed-NV
Cadmium and cadmium compounds	0.05 (inhalation)	4.1 (oral)
Chromium (hexavalent compounds)	0.001 (inhalation)	8.2 (oral)
Lead and lead compounds	15 (oral)	0.5
Nickel compounds	0.4 (subsulfide)	Only carbonyl listed-NV
NV No value. A Safe Harbor Value has not been established.		

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Metals Pathways

- Incidental ingestion (hand-to-mouth)
- Direct dermal contact
- Inhalation of dusts

Exposure Assumptions

- Surface area (for HTM and direct dermal)
- HTM frequency
- Exposure duration/frequency
- Inhalation rate

Clearance Concentrations

- Clearance concentrations are the metal concentration that can be present in a product without receptors being exposed to these metals at levels that exceed the Safe Harbor levels
- Scenarios Considered
  - Frequent use-Desk
  - Infrequent use-hutch
  - Frequent use-soft surface (couch)

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Clearance Concentrations

Clearance Concentrations					
	Desk	Hutch	Couch		
	Oral/Dermal Exposure		Oral Exposure	Dermal Contact	Inhalation
Sample Type	Wipe ($\mu g/cm^2$)	Wipe ($\mu g/cm^2$)	Wipe ($\mu g/cm^2$)	Fabric[b] (mg/kg)	Fabric[b] (mg/kg)
Arsenic	0.058	9.4	0.074	160	190
Cadmium	0.031	5.1	0.030	2,000	160
Chromium (Hexavalent)	0.057	9.3	0.061	400	3
Lead	0.0012	0.19	0.001	700	1600
Nickel (subsulphide)	0.0028	0.45	0.003	20	1300

TAB 4 – Organics (VOCs)

- Benzene
- Dichloromethane
- Methanol
- Toluene

- Note:
  - MIBK was also prioritized however there is currently no NSRL/MADL available so it was not included in the workbook
  - Styrene was added to the list after the workbook was complete and has not been included. Only residual styrene levels are a concern (in polymers and coatings), polystyrene packaging is not included.

VOCs in Furniture

- Composite wood products (i.e., hardwood plywood, particleboard and medium-density fiberboard)
- Fabrics
- Paints
- Dyes
- Finishes

Testing for VOCs

- Total analysis
- Available VOCs
  - Wipe sampling (for hard surfaces)
  - Simulated sweat extract (for hard or soft surfaces)
- Volatile emissions
  - Chamber study

Notes:

- Ensure adequate detection limits
- Wipe sampling is only necessary on products/surfaces known to contain VOCs

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VOCs – NSRL/MADL

Summary of Safe Harbor Levels (µg/day)		
Chemical	NSRL	MADL
Benzene	6.4 – oral 13 – inhalation	24 – oral 49 – inhalation
Dichloromethane	50 - oral 200 - inhalation	Not listed
Methanol	Not listed	23,000 – oral 47,000 - inhalation
Toluene	Not listed	7,000 – oral 13,000 - inhalation
Note: dichloromethane is only listed for cancer endpoints, and methanol and toluene are only listed for developmental endpoints.		

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VOC Pathways

- Vapor inhalation
- Incidental ingestion (hand-to-mouth)
- Direct dermal contact

Exposure Assumptions

- Surface area (for HTM and direct dermal)
- HTM frequency
- Exposure duration/frequency
- Inhalation rate
- Decay rates/product half-life

Pilot Testing-frequent use product

Oral and Dermal Exposure Estimates for Organics from a Desk Compared to the Safe Harbor Levels

Chemical	Wipe conc. (µg/cm^2)	Oral Exposure	Dermal Exposure	Total Exposure	NSRL (µg/day)	MADL (µg/day)	Concentrations Protective of the Safe Harbor Level (µg/cm^2)	
							NSRL	MADL
Benzene	<0.05	6.4	2.3	**8.7**	6.4	24	0.037	0.14
Dichloromethane	<0.05	6.4	2.3	8.7	50	-	0.29	-
Methanol	<0.05	6.4	2.3	8.7	-	23,000	-	130
Toluene	<0.05	6.4	2.3	8.7	-	7,000	-	40

Bolded values highlighted in grey are in excess of one or both of the Safe Harbor Levels.

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Pilot Testing-occasional use product

Oral and Dermal Exposure Estimates for Organics from a Hutch Compared to the Safe Harbor Levels

Chemical	Oral Exposure	Dermal Exposure	Total Exposure	NSRL	MADL	Concentrations Protective of the Safe Harbor Level (µg/cm^2)	
						NSRL	MADL
Benzene	0.039	0.014	0.053	6.4	24	6.0	22
Dichloromethane	0.039	0.014	0.053	50	NV	47	-
Methanol	0.039	0.014	0.053	NV	23,000	-	21,000
Toluene	0.039	0.014	0.053	NV	7,000	-	6,500

NV No value. A Safe Harbor level has not been established; dichloromethane is only listed for cancer endpoints, and methanol and toluene are only listed for developmental endpoints.

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Pilot Testing-fabric product

Oral and Dermal Exposure Estimates for Organics from a Couch Compared to the Safe Harbor Levels

Chemical	Oral Exposure	Dermal Exposure	Total Exposure	NSRL	MADL	Acceptable Concentrations[a]	
						Ingestion ($\mu g/cm^2$)[b]	Dermal Contact (mg/kg)[b]
Benzene	6.75	0.01	6.76	6.4	24	0.05[c]	25.9[c]
Dichloromethane	6.75	0.01	6.76	50	NV	0.37	203
Methanol	6.75	0.01	6.76	NV	23,000	170	93,200
Toluene	6.75	0.01	6.76	NV	7,000	51.9	28,400

Bolded values highlighted in grey are in excess of one or both of the Safe Harbor Levels.

NV No value. A Safe Harbor Level has not been established; dichloromethane is only listed for cancer endpoints, and methanol and toluene are only listed for developmental endpoints.

[a]Acceptable concentrations were back-calculated to be protective of the lower of the Safe Harbor Levels (where applicable) using the exposure parameters specified for each scenario.

[b]When evaluating soft surfaces, acceptable concentrations must be expressed on a $\mu g/cm^2$ and mg/kg basis for incidental ingestion and direct dermal contact, respectively.

[c] Acceptable concentrations were based on meeting the more restrictive of the NSRL and MADL.

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Test Results-chamber test

Comparison of Acceptable Emission Rates Protective of the MADLs to Measured 7-Day Unit Emission Rates for Three Furniture Products (µg/h)

Chemical	Acceptable Emission Rate (µg/h)	Measured 7-Day Emission Rate		
		Nine Drawer Dresser	Executive Office Desk	China Hutch
Benzene	300	<7.9	<8.7	<35
Dichloromethane	NA	<17,000	<19,000	<75,000
Methanol	290,000	<5,100	<5,700	<23,000
Toluene	79,000	53	<8.7	<35

NA Not applicable. A Safe Harbor Level has not been established for this endpoint; dichloromethane is only listed for cancer endpoints.

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Summary

- Workbooks have been developed to help AHFA members to make decisions regarding Prop 65
- Unfortunately, Prop 65 benchmarks are exposure based and require product specific testing and evaluation in order to inform the decision-making process
- The workbooks are designed to facilitate the evaluation; however, every product can be different
- Members should seek legal advice in connection with any exposure assessment.