RISK ASSESSMENT REPORT

TITLE:	**EXPOSURE RISK ASSESSMENT FOR**
AUTHOR(S):	
COMPLETED ON:	February 15, 2011
CAS # :	71-43-2, 50-00-0, 108-88-3, 100-41-4
CHEMICAL NAME:	Benzene [71-43-2], Formaldehyde [50-00-0], Toluene [108-88-3], Ethyl benzene [100-41-4]
REPORT #:	

1.0 Scope

The business requested a consumer exposure screening assessment to address the PROP 65 labeling requirement for California in regards to four components present in the

If it can be demonstrated that consumers would not be exposed at the concentrations listed for PROP 65, then no labeling is required for products going into California. The compounds to be assessed are benzene, formaldehyde, toluene and ethyl benzene. The scenario addresses both the inhalation and dermal pathways for potential exposure from use of the product by consumers. Extremely conservative assumptions were used, for example it was assumed that all the material could go 100% to either the dermal pathway or to the inhalation pathway which of course is not realistic.

2.0 Summary

The exposure screening assessment for benzene, formaldehyde, toluene, and ethyl benzene supports the conclusion that potential exposure is below the PROP 65 health benchmarks. The exposure estimates are considered very conservative. Margins of safety were all greater than 1 indicating safe use.

Table 1: Results for Exposure Estimates and Margins of Safety compared to MADLs

Substance	Inhalation Exposure Estimate (μg/day)	Inhalation Exposure Margin of Safety	Dermal Exposure Estimate (μg/day)	Dermal Exposure Margin of Safety
Benzene	1	49	0.2	120
Toluene	91	77	2700	3

Table 2: Results for Exposure Estimates and Margins of Safety compared to NSRLs

Substance	Inhalation Exposure Estimate (μg/day)	Inhalation Exposure Margin of Safety	Dermal Exposure Estimate (μg/day)	Dermal Exposure Margin of Safety
Benzene	0.02	650	5E-03	1200
Formaldehyde	0.02	2000	0.5	80
Ethyl benzene	42	1.3	0.09	450

Margin of Safety = PROP 65 health benchmark/exposure estimate, >1 required

3.0 Background information on Health Benchmarks

The California Office of Environmental Health Hazard Assessment (OEHHA) lists the most Current Proposition 65 No Significant Risk Levels (NSRLs) and Maximum Allowable Dose Levels (MADLs) at their website: http://oehha.ca.gov/prop65/getNSRLs.html. The levels are listed in Table 3 for the relevant substances. NSRLs are for long term exposure related to carcinogens and MADLs are typically compared to exposure on the day of exposure. Thus time averaging can be considered for NSRLs but not for MADLs.

Table 3: PROP 65 Health benchmarks

Substance	CAS #	MADL (μg/day)	NSRL (μg/day)
Benzene	71-43-2	24 (oral) 49 (inhalation)	6.4 (oral) 13 (inhalation)
Formaldehyde	50-00-0	NA	40
Toluene	108-88-3	7000	NA
Ethylbenzene	100-41-4	NA	41 (oral) 54 (inhalation)

NA = not applicable
(oral): when PROP 65 lists the oral route, the estimated dermal absorbed dose will be compared this value
(inhalation): when PROP 65 lists the inhalation route, the estimated inhalation exposure will be compared to this value.

4.0 Exposure Scenario and Exposure Estimation Approach

The consumer is expected to use 25% of the container in one session. The container holds 4 ml of product with 1 ml used for each scenario. It takes 60 minutes to apply 1 ml of product and the consumer is assumed to complete no more than once a month. The has a density close to 1.0 g/ml since 77.6% of the material has a specific gravity in the range of 0.87 and 0.96, with water being 1.0. The higher density value results in a conservative exposure estimation. With these characteristics for the formulation, a density of 1 g/ml was assumed for . Table 4 contains the information provided from the business on the composition of

Table 4: Substance concentration in

Substance	Vapor Pressure at 25°C (mm Hg)	Wt% in car repair stick	Amount per use assuming 1/4th stick used per use (mg)
Benzene	95	0.003	0.03
Formaldehyde	3490	0.002	0.02
Toluene	28.4	0.27	2.7
Ethylbenzene	9.6	5.21	52.1

Note Chemical concentration assumes has a density of 1 g/ml (see paragraph above).

Both the inhalation route and the dermal were considered. is not expected to be ingested so no oral exposure is considered. The activity of applying product and removing excess product was considered. The substances are all very volatile indicating that inhalation is the predominant route. Dermal exposure is possible if the fingertips are used to remove excess product rather than a cloth.

Inhalation Exposure

To estimate the inhalation exposure for the 1 hour application event, CONSEXPO 4.1, a consumer exposure model, was used. The product should be applied outdoors as sunlight (UV)

is needed to cure the polymeric substances present and temperatures need to be above 50°F. To estimate a worst case inhalation exposure, it was assumed that was applied in a 20 m^3 with the door open resulting in 2 air exchanges per hour. CONSEXPO uses the box model to estimate the concentration in a defined room volume based on the amount of mass present and assuming it is released constantly during use into the room volume. The model estimates the inhalation exposure for the 1 hour scenario using the following Tier 1 assessment in Equation 2.

ConsExpo Formula for Tier 1 (Constant Release) is

$$C_{air} = \frac{A_o \times w_f / t_r}{qV} \times (1 - e^{-qt_r}) \times e^{-q(t-t_r)} \qquad \text{(Equation 1)}$$

where:

C_{air}	: concentration of compound in the room air	[kg/m^3]
t_r	: release time	[s]
A_o	: amount of product used	[kg]
wf	: weight fraction of the compound in the product	[fraction]
V	: room volume	[m^3]
q	: ventilation rate of the room (number of air changes per time)	[1/s]
t	: time of exposure	[s]

The estimate from CONSEXPO is then input into EPA equation to calculate the long term chronic inhalation exposure based on EPA Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) from December 1989 (EPA, 1989). Equation 3 (Exhibit 6-16 in EPA, 1989) provides the inhalation exposure from inhalation of airborne chemicals.

$$\text{Inhalation (mg/day)} = \frac{\text{CA x IR x ET x EF x ED}}{\text{AT}} \qquad \text{(Equation 2)}$$

Where

CA= concentration in air during scenario (mg/m3)	from Consexpo
IR = inhalation rate m^3/hr	used 2.4 m^3/hr (EPA, 2009)
ET = exposure time (hrs/day):	used 1 hour/day
EF = exposure frequency (days/year):	used 12 days/year
ED = exposure duration (years):	used 50 years
AT = averaging time (days):	equals 70 yrs x 365 day/yr = 25550 days for NSRLs
AT = averaging time (days):	not used for MADL

Dermal Exposure

Dermal exposure is assessed based on EPA Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part E) from July 2004 (EPA, 2004). This guidance has two equations (3-1 for water contact and 3-11 for soil contact). The equations are the same except

for how the absorbed dose per event (DA) is calculated and is represented by Equation 6. The is a solvent contact so the absorbed dose is calculated differently thant would be calculated for water contact or soil. . Worst case dermal exposure would be for a consumer to use a couple of fingertips to wipe excess product instead of a cloth as recommended. The area of 10 fingertips is equivalent to approximately 20 cm^2 (2 cm^2 per fingertip is assumed) and allow for 2 wipes per fingertip results in a potential dermal exposure to 40 cm^2. It is expected that the hands are washed once the job is completed. It is assumed that a consumer could apply the once a month for 50 years which will address a long term use. Again this is an extremely conservative assumption. For PROP 65 health benchmarks are not divided by body weight (BW) so it is not used in the calculation and final results are mg/day. Since the substances are so volatile, dermal absorption is not expected to be the main exposure route. The simplest and most conservative approach for dermal exposure is too assume all the mass of substance present in the material contacts the skin and is completely absorbed.

DA = Dermal dose (mg) = M (Equation 3)

A more refined approach can take into account the skin area contacted, the time on the skin, the flux of the substance through the skin (Keil, 2009)

DA = Flux x T x SA (Equation 4)

Where

M = mass substance available per use (mg/event) Table 3

Flux = steady state flux of substance through skin (mg/hr/cm2) based on measured data
T = time substance remains on skin (hr) based on Equation 5
SA = skin surface area available for contact (cm2): used 40 cm^2

For volatile substances there is a refinement to account for the fact that it continues to evaporate during the exposure reducing the mass available for dermal absorption. This reduces the time substance remains on skin. An equation was derived (Gmehling and Weidlich, 1986) based on mass transfer at the interface between the liquid and the vapour. This equation was recommended for use in tthe EU REACH registrations. European Chemicals Agency (ECHA) Guidance on information requirements and chemical safety assessment, R14: Occupational exposure estimation, Appendix 14.1 to reduce the mass available for dermal absorption based on the vapor pressure of the substance.

$$t_{(s)} = \frac{mRT}{M\beta pA} K \quad \text{(Equation 5)}$$

t:	Time on skin per day	answer	[s]
m:	mass, available	input	[mg]
R:	gas constant:	8.314	[$J.K^{-1}.mol^{-1}$]
T:	skin temperature	293	[K] (20°C – conservative estimate)
M:	molar mass	input	[g/mol]

β:	coefficient of mass transfer in the vapour phase [m h^{-1}], for calculation: β = 8.7 m/h		
p:	vapour pressure of the pure substance	input	[Pa]
A:	Skin area,	40	cm^2
K:	conversion factor:	3.60E+04	3.6 x 10^4

Where the coefficient of mass transfer, β, is described based on empirical studies and the main influencing parameter is the velocity of air. A conservative value of 0.3 m/s for the velocity of air was used to estimate β and comparisons to measured data indicate that the estimate is within 5% of measured data.

The additional refinements (Equation 4 and 5) are only implemented if Equation 3 leads to results above the MADL and NSRL consistent with the tiered risk assessment approach. The resultant average daily dose is then calculated by using Equation 6.

$$\text{Average Dermal Daily Dose (mg/day)} = \frac{DA \times EV \times EF \times ED}{AT} \qquad \text{(Equation 6)}$$

Where:
DA = dermal absorbed dose for event (mg/event) Equation 3 or 4
EV = event frequency (events/day): used 1 time/day
EF = exposure frequency (days/year): used 12 days/year
ED = exposure duration (years): used 50 years
AT = averaging time (days): equals 70 yrs x 365 day/yr = 25550 days for NSRLs
AT = averaging time (days): not used for MADL

Note the ED and the AT can be different. EPA uses 70 years for the averaging time for carcinogenic effects but the actual exposure time can be less than 70 years. A consumer is not expected to for their entire lifetime but for the active adult years for which 50 years is a conservative estimate. For MADLs there is no averaging over time so AT =1 day. Therefore a chronic estimate will be derived for comparison to the NSRLs and a short term estimate will be derived for comparison to the MADLs.

4.1 Benzene Exposure Assessment

Benzene is identified as a carcinogen and a reproductive toxicant for PROP 65 and therefore has both NSRL and MADLs for comparison to exposure estimates.

Inhalation Exposure Estimate
The CONSEXPO inhalation model was run for constant release, the result was 0.0004 mg/m^3 which was then used in Equation 2 to estimate the long term (chronic) inhalation exposure and the daily inhalation exposure. The CONSEXPO inputs and outputs for benzene are included in the Appendix. All the parameters are the same for each substance except for the amount of substance present.

Short term inhalation exposure estimate (mg/day) =
0.0004 mg/m3 x 2.4 m^3/hr x 1 hr/day = 9.6E-04 mg/day = 0.96 μg/day or 1μg/day

Chronic inhalation exposure estimate (mg/day) =

$$\frac{0.0004\ mg/m^3 \times 2.4\ m^3/hr \times 1\ hr/day \times 12\ days/yr \times 50\ years}{25550\ day} = 2.25E\text{-}05\ mg/day = 0.023\ \mu g/day$$

or 0.02 μg/day.

Dermal Exposure Estimate
Equation 4, 5 and 6 were used to estimate the refined dermal absorbed dose for benzene since Equation 3 (extremely conservative) results in a dermal absorbed dose that well exceeds the MADL. A literature search revealed that a conservative estimate for the flux of benzene into skin for a solvent application would be 2 mg/cm^2/hr or 5.6E-04 mg/cm^2/sec (Nies, 2008).

The estimated time on skin is for the entire 30 μg of benzene is 8E-03 seconds. This result is then used in Equation 4 to estimate the dermal dose.

DA= Dermal absorbed Dose per event = 5.6E-04 mg/cm^2/sec x 8E-03 sec x 40 cm^2 = 2E-04 mg/event or 0.2 μg/event

Short term Dermal Absorbed dose = 0.2 μg/day, assuming 1 event/day

Chronic Dermal Absorbed dose =

$$\frac{0.2\ \mu g/event \times 1\ event/day \times 12\ days/yr \times 50\ years}{25550\ days} = 5E\text{-}03\ \mu g/day$$

The exposure estimates for both Chronic and short term dermal and inhalation exposure are below the PROP 65 health benchmarks. Refer to Table 1 and 2 for margins of safety.

4.2 Formaldehyde Exposure Assessment

Formaldehyde is identified as a carcinogen for PROP 65 and therefore has a NSRL for comparison to exposure estimates.

Inhalation Exposure Estimate
The CONSEXPO inhalation model was run for constant release, the result was 2.8E-04mg/m^3 which was then used in Equation 2 to estimate the long term (chronic) inhalation exposure.

Chronic inhalation exposure estimate (mg/day) =

$$\frac{2.8E\text{-}04\ mg/m^3 \times 2.4\ m^3/hr \times 1\ hr/day \times 12\ days/yr \times 50\ years}{25550\ days} = 2E\text{-}05\ mg/day$$

or 0.02 μg/day

Dermal Exposure Estimate
The dermal absorbed dose was calculated using Equation 3 and 6.

DA= Dermal absorbed dose per event = Mass from table 4 = 0.02 mg/event

Chronic Dermal Absorbed dose $\frac{=0.02 \text{ mg/event} \times 1 \text{ event/day} \times 12 \text{ days/yr} \times 50 \text{ years}}{25550 \text{ days}}$ = 5E-04 mg/day
Dermal Absorbed dose = 0.5 μg/day

The exposure estimates for both dermal and inhalation exposure are below the PROP 65 health benchmarks. Refer to Table 2 for margins of safety.

4.3 Toluene Exposure Assessment

Toluene is identified as a reproductive toxicant for PROP 65 and therefore has a MADL for comparison to exposure estimates.

Inhalation Exposure Estimate
The CONSEXPO inhalation model was run for constant release; the result was 0.038 mg/m^3 which was then used in Equation 2 to estimate the inhalation exposure without time averaging.

Short term Inhalation exposure estimate (mg/day) =
0.038 mg/m^3 x 2.4 m^3/hr x 1 hr/day = 0.091 mg/day or 91 μg/day

Dermal Exposure Estimate
The dermal absorbed dose was calculated using Equation 3 and 6.

Short term dermal absorbed dose = 2.7 mg/event x 1 event/day = 2.7 mg/day or 2700 μg/day

The exposure estimates for both dermal and inhalation exposure are below the PROP 65 health benchmarks even using the very conservative dermal approach. Refer to Table 1 for margins of safety.

4.4 Ethyl benzene Exposure Assessment

Ethyl benzene is identified as a carcinogen for PROP 65 and therefore has a NSRL for comparison to exposure estimates.

Inhalation Exposure Estimate
The CONSEXPO inhalation model was run for constant release, the result was 0.738 mg/m^3 which was then used in Equation 2 to estimate the long term (chronic) inhalation exposure.

Chronic inhalation exposure estimate (mg/day) =
$\frac{0.738 \text{ mg/m}^3 \times 2.4 \text{ m}^3\text{/hr} \times 1 \text{ hr/day} \times 12 \text{ days/yr} \times 50 \text{ years}}{25550 \text{ days}}$ = 0.042 mg/day or 42 μg/day

Dermal Exposure Estimate
The dermal absorbed dose was calculated using Equation 4, 5 and 6.

Equation 4, 5 and 6 were used to estimate the dermal absorbed dose for benzene since Equation 3 results in a dermal absorbed dose that well exceeds the MADL. A literature search revealed that a conservative estimate for the flux of ethyl benzene into skin in a solvent application would be 3.32 $\mu g/cm^2/hr$ or 9.2E-04 $\mu g/cm^2/sec$ (Muhammad, 2005).

The estimated time on skin for the entire 52 mg (from Table 4) of ethyl benzene is 97 seconds. This result is then used in Equation 4 to estimate the dermal dose.

Dermal Dose = 9.2E-04 $\mu g/cm^2/sec$ x 97 sec x 40 cm^2 = 3.6 μg/event

Chronic Dermal Absorbed dose =

$$\frac{3.6\ \mu g/event \times 1\ event/day \times 12\ days/yr \times 50\ years}{25550\ days} = 0.09\ \mu g/day$$

The exposure estimates for both dermal and inhalation exposure are below the PROP 65 health benchmarks. Refer to Table 2 for margins of safety.

5.0 Uncertainty Discussion

These parameters used for the calculations were chosen to be conservative. The chronic use scenario of once per month, the length of time and quantity of product use were all chosen to be worst case For the inhalation calculations exposure was considered inside with reasonable ventilation versus outside where there would be much more dilution of any volatile components and the area would be greater than 20 m^3. The inhalation rate of 2.4 m^3/hr is from Table 6-2 of the EPA Exposures Factors handbook. It represents the 95th percentile for moderate activity which is extremely conservative for this type of activity. This inhalation rate was used for the exposure assessment and was selected for consistency. A low activity inhalation rate could have been used which would result in lower inhalation exposures. For the dermal exposure assessment formaldehyde and toluene were assumed to be 100% absorbed which results in an overestimate of exposure. The dermal refinement of using the flux from experimental data is based on neat absorption and the most conservative estimate was used which for the ethyl benzene data was on skin that had already been exposed to jet fuel resulting in higher flux than fresh skin was exposed to ethyl benzene (Muhammad, 2005). Neat benzene dermal flux has been extensively studied and the most conservative dermal flux was used (Nies, 2008).

6.0 References

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Appendix 1: CONSEXPO 4.1 Input and Output from Constant Release Inhalation Model

ConsExpo 4.1 report for Benzene

Report date: 2/8/2011

Product

Compound

Compound name :	benzene	
CAS number :		
molecular weight		g/mol
vapour pressure		Pascal
KOW		10Log

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0.003	%
exposure duration	60	minute
room volume	20	m3
ventilation rate	2	1/hr
applied amount	1E3	milligram
release duration	60	minute

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.000425	mg/m3

ConsExpo 4.1 report for Formaldehyde

Report date: 2/8/2011

Product

Compound

Compound name :	formaldehyde	
CAS number :		
molecular weight		g/mol
vapour pressure		Pascal
KOW		10Log

General Exposure Data

exposure frequency	12	1/year
body weight	58	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0.002	%
exposure duration	60	minute
room volume	20	m3
ventilation rate	2	1/hr
applied amount	1E3	milligram
release duration	60	minute

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.000283	mg/m3

ConsExpo 4.1 report for Toluene

Report date: 2/8/2011

Product

Compound

Compound name :	toluene	
CAS number :		
molecular weight		g/mol
vapour pressure		Pascal
KOW		10Log

General Exposure Data

exposure frequency	12	1/year
body weight	58	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	0.27	%
exposure duration	60	minute
room volume	20	m3
ventilation rate	2	1/hr
applied amount	1E3	milligram
release duration	60	minute

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.0383	mg/m3

ConsExpo 4.1 report for Ethyl Benzene

Report date: 2/8/2011

Product

Compound

Compound name :	ethyl benzene	
CAS number :		
molecular weight		g/mol
vapour pressure		Pascal
KOW		10Log

General Exposure Data

exposure frequency	12	1/year
body weight	58	kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound	5.21	%
exposure duration	60	minute
room volume	20	m3
ventilation rate	2	1/hr
applied amount	1E3	milligram
release duration	60	minute

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.738	mg/m3