RISK ASSESSMENT REPORT

TITLE:	**EXPOSURE RISK ASSESSMENT FOR**
AUTHOR(S):	
COMPLETED ON:	December 17, 2010
CAS # :	71-43-2, 50-00-0, 109-86-4
CHEMICAL NAME:	Benzene, Formaldehyde, Ethylene glycol monomethyl ether
REPORT #:	

1.0 Scope

The business requested a consumer exposure screening assessment to address the PROP 65 labeling requirement for California in regards to 3 components present in . 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 and ethylene glycol monomethyl ether (EG). The scenario addresses both the dermal and inhalation 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 both the dermal and inhalation pathways which of course is not realistic.

2.0 Summary

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

Table 1: Results for Exposure Estimates and Margins of Safety

Substance	Dermal Exposure Estimate (μg/day)	Dermal Exposure Margin of Safety	Inhalation Exposure Estimate (μg/day)	Inhalation Exposure Margin of Safety
Benzene	1.4	3	1.8	7
Formaldehyde	2.5	16	27	1.5
Ethylene glycol monomethyl ether	2.1	357	233	4

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 2 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 2: PROP 65 Health benchmarks

Substance	CAS #	MADL (μg/day)	NSRL (μg/day)
Benzene	71-43-2	NA	6.4 (oral) 13 (inhalation)
Formaldehyde	50-00-0	NA	40
Ethylene glycol monomethyl ether	109-86-4	750 (oral) 960 (inhalation)	NA

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 ½ of the container in one session. The container holds 500 grams of product so 250 grams is used for each scenario. It takes one hour to apply and remove and the consumer is assumed to once a month. The contains 69-72% water. A density of 1 g/ml was assumed for the . Table 3 contains the information provided from the business on the composition of .

Table 3: Substance concentration

Substance	Wt% in	Chemical concentration in water(or) (mg/L)	Amount per use (mg per 250 g)
Benzene	0.0003	3	0.75
Formaldehyde	0.0045	45	11.25
Ethylene glycol monomethyl ether	0.0009	9	2.25

Note Chemical concentration assumes has a density of 1 g/ml which is reasonable since it is 70% water.

Both the dermal and the inhalation route shall be considered. is not expected to be ingested so no oral exposure is considered. The activity of applying and removing was considered.

Dermal Exposure

Dermal exposure is assessed based on EPA Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) from December 1989 (EPA, 1989). Equation 1 (Exhibit 6-13 in EPA, 1989) provides the dermal exposure from dermal contact with chemicals in water. The EPA Exposure Factors handbook was consulted to determine the skin area exposed (EPA, 2009). Worst case dermal exposure would be for the entire two hands. The EPA Exposure Factors handbook (Table 7-2) lists the 95th percentile for adult males as 1310 cm^2. Female hands are slightly smaller so the 1310 cm^2 is a worst case. Once gets on the hands it is assumed to stay there for the entire one hour time. It is expected that the hands are washed once the job is completed. It is assumed that a consumer could polish cars once a month for 50 years which will address a long term use. Again this is an extremely conservative selection. 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.

$$\text{Absorbed dose (mg/kg/day)} = \frac{CW \times SA \times Kp \times ET \times EF \times ED \times CF}{BW \times AT} \quad \text{(Equation 1)}$$

Where:

CW = chemical concentration in water (mg/Liter) see Table 3

SA = skin surface area available for contact (cm2): used 1310 cm^2
Kp = dermal permeability coefficient (cm/hr) chemical specific
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
CF = conversion factor (L/cm^3): equals 0.001 L/cm^3
BW = body weight (kg): not used for PROP 65
AT = averaging time (days): equals 70 yrs x 365 day/yr = 25550 days for NSRLs

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 for their entire lifetime but for the active adult years for which 50 years is a conservative estimate.

Inhalation Exposure

Since the substances are volatile, the inhalation exposure was also estimated to verify no significant contribution to the overall dose. To estimate the inhalation exposure for the 1 hour application event, CONSEXPO 4.1, a consumer exposure model, was used. To estimate a worst case inhalation exposure, it was assumed that was applied in 20 m^3 with the doors closed resulting in a very low air exchange rate of a newer well sealed house (0.3 m^3/hr). CONSEXPO uses the box model to estimate the concentration in a defined room volume based on the amount of mass present and assuming it all is released instantaneously 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 (Instantaneous Release) is

$$C_{average} = \frac{A \times w_f}{V} \times \frac{1}{T} \int e^{-qt} = \frac{A \times w_f}{V} \times \frac{1}{T} \times [1 - e^{-qt}] \qquad \text{(Equation 2)}$$

Where

A = product amount applied, mg
wf = weight fraction of substance in product
V = volume (m^3)
q = air exchanges/hr
t = exposure time in hrs
T = q*t

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.

$$\text{Inhalation (mg/kg/day)} = \frac{CA \times IR \times ET \times EF \times ED}{BW \times AT} \qquad \text{(Equation 3)}$$

Where

CA= concentration in air during scenario (mg/m3)	from Consexpo
IR = inhalation rate m^3/hr	used 2.4 m^3/hr
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
BW = body weight (kg):	not used for PROP 65
AT = averaging time (days):	equals 70 yrs x 365 day/yr = 25550 days for NSRLs

4.1 Benzene Exposure Assessment

Benzene is identified as a carcinogen for PROP 65 and therefore has a NSRL for comparison to exposure estimates. This means Equation 1 was used to estimate the dermal absorbed dose for benzene with the time averaging component intact. The Kp of 1.5E-02 cm/hr for benzene was obtained from the EPA Risk Assessment guidance for Superfund Volume I: Human Health Evaluation Manual, Part E, Exhibit B-2. Section 5.2.2.1 (page 5-5) of this guidance recommends using the predicted Kp from Exhibit B-2 in Equation 1.

Dermal Absorbed dose =

$$\frac{3\ mg/L \times 1310\ cm^2 \times 0.015\ cm/hr \times 1\ hr/day \times 12\ days/yr \times 50\ years \times 0.001\ L/cm^3}{25550\ days}$$

Chronic Dermal Absorbed dose = 0.00138 mg/day or 1.4 μg/day

The CONSEXPO inhalation model was run for instantaneous release, the result was 0.0324 mg/m^3 which was then used in Equation 3 to estimate the long term (chronic) 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.

Chronic inhalation exposure estimate (mg/day) =

$$\frac{0.0324\ mg/m^3 \times 2.4\ m^3/hr \times 1\ hr/day \times 12\ days/yr \times 50\ years}{25550\ days} = 1.83E\text{-}03\ mg/day$$

or 1.8 μg/day

The exposure estimates for both dermal and inhalation exposure are below the PROP 65 health benchmarks. Refer to Table 1 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. This means Equation 1 was used to estimate the dermal absorbed dose for formaldehyde with the time averaging component intact. The Kp of 1.8E-03

cm/hr was obtained from the EPA Risk Assessment guidance for Superfund Volume I: Human Health Evaluation Manual, Part E, Exhibit B-2.

Dermal Absorbed dose =

$$\frac{45\ mg/L \times 1310\ cm^2 \times 0.0018\ cm/hr \times 1\ hr/day \times 12\ days/yr \times 50\ years \times 0.001\ L/cm^3}{25550\ days}$$

Dermal Absorbed dose = 0.0025 mg/day or 2.5 ug/day

The CONSEXPO inhalation model was run for instantaneous release, the result was 0.486 mg/m^3 which was then used in Equation 2 to estimate the long term (chronic) inhalation exposure.

Chronic inhalation exposure estimate (mg/day) =

$$\frac{0.486\ mg/m^3 \times 2.4\ m^3/hr \times 1\ hr/day \times 12\ days/yr \times 50\ years}{25550\ days} = 0.0274\ mg/day$$

or 27 ug/day

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

4.3 Ethylene glycol monomethyl ether (EG) Exposure Assessment

EG is identified as a reproductive and developmental toxicant for PROP 65 and therefore has a MADL for comparison to exposure estimates. This means Equation 1 was used to estimate the dermal absorbed dose for EG without the time averaging component intact. The exposure is estimated per use and this value is compared to the MADL. The Kp of 1.8E-04 cm/hr for EG was obtained from the EPA Risk Assessment guidance for Superfund Volume I: Human Health Evaluation Manual, Part E, Exhibit B-2.

Dermal Absorbed dose = 9 mg/L x1310 cm^2 x 0.00018 cm/hr x 1 hr/day x 0.001 L/cm^3

Dermal Absorbed dose = 0.00212 mg/day or 2.1 μg/day

The CONSEXPO inhalation model was run for instantaneous release, the result was 0.0972 mg/m^3 which was then used in Equation 2 to estimate the inhalation exposure without time averaging.

Inhalation exposure estimate (mg/day) =

0.097 mg/m^3 x 1.5 m^3/hr x 1 hr/day = 0.146 mg/day or 146 ug/day

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

5.0 References

CONSEXPO, 2010. CONSEXPO 4.1 model, National Institute for Public Health and the Environment (RIVM), Netherlands, available to download at: http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp

EPA, 2004. EPA Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual, Part E, Supplemental Guidance for Risk Assessment, Final, 2004.

EPA, 1989. EPA Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual, Part A, Interim Final, 1989.

EPA 2009, EPA Exposure Factors Handbook, 2009 Update for final review.

Appendix 1: CONSEXPO 4.1 Input and Output from Instantaneous Inhalation Model

ConsExpo 4.1 report

Report date: 12/14/2010

Product

Compound

Compound name :	benzene	
CAS number :		
molecular weight		g/mol
vapour pressure		mmHg
KOW		linear

General Exposure Data

exposure frequency	1	1/month
body weight	65	kilogram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	1	fraction
exposure duration	60	minute
room volume	20	m3
ventilation rate	0.3	1/hr
applied amount	750	microgram

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	34.7	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	0.0324	mg/m3 **(*** number used)**
inhalation mean concentration on day of exposure:	0.00135	mg/m3
inhalation air concentration year average :	4.44E-5	mg/m3/day
inhalation acute (internal) dose :	0.00072	mg/kg
inhalation chronic (internal) dose :	2.37E-5	mg/kg/day

[redacted]