

RISK ASSESSMENT REPORT

TITLE:	PROP 65 EXPOSURE RISK ASSESSMENT FOR FORMALDEHYDE AND ACETALDEHYDE IN
AUTHOR(S):	
COMPLETED ON:	October 5, 2012
CAS # :	50-00-0 and 75-07-0
CHEMICAL NAME:	Formaldehyde and Acetaldehyde
REPORT #:	

1.0 SCOPE

As part of a product stewardship review for [redacted] an exposure assessment was performed.

The California Office of Environmental Health Hazard Assessment (OEHHA) has both formaldehyde and acetaldehyde listed as a carcinogen on the Proposition 65 list for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (OEHHA, 2012). OEHHA has developed the safe harbor for inhalation, referred to as the No Significant Risk Level (NSRL) at 90 µg/day for acetaldehyde and 40 µg/day for formaldehyde. The scenario considered is a person spending all day in a room with [redacted] (110.5 in² surface area). Both substances are volatile so only inhalation exposure is considered.

2.0 SUMMARY

The exposure screening assessment for formaldehyde and acetaldehyde supports the conclusion that potential exposure is below PROP 65 health benchmarks. Risk characterization ratios were below 1 indicating that safe harbor was met and no labeling is required. In Table 1 results are presented with the detailed exposure approach following in section 3.0.

Table 1: Results for Exposure Assessment

Substance	Wt%	Inhalation Exposure (µg/day)	NSRL (µg/day)	Risk Characterization Ratio (must be <1)
Formaldehyde	8E-05	11	40	0.3
Acetaldehyde	0.023	35	90	0.4

3.0 INHALATION EXPOSURE

The scenario is to assume that all the residual acetaldehyde and formaldehyde in [redacted] offgasses from [redacted] into one room and a person stays in room for 8 hours. The product information was supplied by the business.

Basis weight = 54.4 g/m²
Wt% of acetaldehyde in [redacted] = 0.023
Wt% of formaldehyde in [redacted] = 8E-05
Wt% of [redacted] applied = 10 %
Surface area of one [redacted] = 110.5 in² (0.071 m²)
Basis weight of [redacted] = 54.4 g/m²
Mass of [redacted] in room = 0.071 m² x 54.4 g/m² = 3.9 g
Mass of [redacted] in room = 3.9 g x 0.1 = 0.39 g
Mass of acetaldehyde in room = 0.39 g x 0.00023 = 9E-05 g or 90 µg
Mass of formaldehyde in room = 0.39 g x 8E-07 = 3E-07 g or 0.3 µg
Room size = 10 m³
Air Exchange rate = 0.1/hr (conservative)
Inhalation rate = 1.25 m³/hr for 8 hrs of exposure = 10 m³

The CONSEXPO 4.1 inhalation to vapor model was used to predict room air concentrations of formaldehyde and acetaldehyde that workers might potentially be exposed to (CONSEXPO, 2010). The model assumes that the room is well mixed and calculates the average concentration for the exposure period based on the mass available in the product. The model estimates concentration as mg/m³ which is then multiplied by the volume of air inhaled during the exposure period to obtain the mg/day exposure for comparison to the NSRL. This model was developed by National Institute for Public Health and Environment (RIVM) of the Netherlands and is accepted for the European REACH regulation. Modeling was performed with the conservative assumption that substances are released instantaneously into the room during the exposure period and that the worker or consumer spends the entire exposure period in this room. Since substance air concentrations are not expected to exceed vapor saturation there is no need for any substance specific properties for this screening level model. The model inputs and outputs are attached in the appendix.

Acetaldehyde Calculations

CONSEXPO instant release rate exposure estimation = 0.0062 mg/m³

Exposure estimation for person spending 8 hr/day in room = 10 m³/day x 0.0062 mg/m³
=0.062 mg/day or 62 µg/day

This is the daily exposure and must be converted into a lifetime average daily dose (LADI) by including the exposure duration with is 40 years for PROP 65 and the cancer averaging time (70 years in days). So the assessment is extremely conservative since it assumes daily exposures for 8 hrs/day for 40 years.

LADI = $\frac{62 \text{ } \mu\text{g/day} \times 1 \text{ event/day} \times 365 \text{ days/yr} \times 40 \text{ years}}{25550 \text{ days}}$ = 35 µg/day

Formaldehyde Calculations

CONSEXPO instant release rate exposure estimation = 2E-05 mg/m³

Exposure estimation for person spending 8 hr/day in room = 10 m³/day x 2E-05 mg/m³
=2E-04 mg/day or 20 µg/day

This is the daily exposure and must be converted into a lifetime average daily dose by including the exposure duration which is 40 years for PROP 65. So assessment is extremely conservative since it assumes daily exposures for 8 hrs/day for 40 years.

LADI = $\frac{20 \text{ } \mu\text{g/day} \times 1 \text{ event/day} \times 365 \text{ days/yr} \times 40 \text{ years}}{25550 \text{ days}}$ = 11 µg/day

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>

OEHHA, 2012. Latest NSRLs and MADLs were downloaded in Sept 2012 from website:

<http://oehha.ca.gov/prop65/pdf/090412Safeharbor.pdf>

APPENDIX

ConsExpo 4.1 report for Formaldehyde

Product

Compound

Compound name : Formaldehyde gram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	1	fraction
exposure duration	8	hour
room volume	10	m ³
ventilation rate	0.1	1/hr
applied amount	0.3	microgram

Output

Inhalation (point estimates)

inhalation mean event concentration : 2.07E-5 mg/m³

ConsExpo 4.1 report for Acetaldehyde

Product

Compound

Compound name : Acetaldehyde gram

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	1	fraction
exposure duration	8	hour
room volume	10	m ³
ventilation rate	0.1	1/hr
applied amount	90	microgram

Output

Inhalation (point estimates)

inhalation mean event concentration : 0.0062 mg/m³