

November 23, 1990

DRAFT DO NOT SITE OR QUOTE

Review and Comparison of Acceptable Ambient Air Concentrations for Vinyl Chloride Based on Carcinogenicity

There are two recent EPA documents in which estimates were derived for ql^* values for vinyl chloride. In the first document (Health Effects Assessment for Vinyl Chloride, EPA, 1984, Office of Health and Environmental Assessment, EPA/540/1-86-036) the human ql^* was determined to be $2.5 \times 10^{-2} (\text{mg/kg/day})^{-1}$. Inhalation studies in rats were used and total tumors were used as the toxicological endpoint. This ql^* value can be converted to units of ppm^{-1} or $(\text{ug}/\text{m}^3)^{-1}$ as follows:

1. correction for surface area between humans and rats

$$[(1/(70\text{kg human}/.35\text{ kg rat}))^{1/3}] * 2.5 \times 10^{-2} = 4.27 \times 10^{-3} (\text{mg/kg/day})^{-1}$$

2. adjustment for body weight of rat

$$4.27 \times 10^{-3} / .35\text{ kg rat} = 1.22 \times 10^{-2} (\text{mg/day})^{-1}$$

3. adjustment for breathing rates of rats

$$.233\text{ m}^3/\text{d} * 1.22 \times 10^{-2} = 2.72 \times 10^{-3} (\text{mg}/\text{m}^3)^{-1} \text{ or}$$

$$2.72 \times 10^{-6} (\text{ug}/\text{m}^3)^{-1} \text{ or}$$

$$2.56 \times 10^3 (\text{ug}/\text{m}^3 * \text{ppm}) * 2.72 \times 10^{-6} (\text{ug}/\text{m}^3)^{-1} =$$

$$6.96 \times 10^{-3} \text{ ppm}^{-1}$$

In a more recent update (Health and Environmental Effects Profile for Chloroethene, EPA, 1985, Environmental Criteria and Assessment Office ECAO-Cinn-P155) the human ql^* was determined to be $2.95 \times 10^{-1} (\text{mg/kg/day})^{-1}$. The same animal studies were used, only instead of using total tumor incidence, just angiosarcomas of the liver were used as the toxicological endpoint. Also, corrections to the dose were made since the observation period was extended after exposure stopped and an assumption was made that only 50% of the inhaled vinyl chloride was being absorbed. By using the same conversion factors above and correcting for % uptake the following inhalation ql^* was determined.

1. correction for surface area between humans and rats

$$[(1/(70/.35))^{1/3}] * 2.95 \times 10^{-1} (\text{mg/kg/d})^{-1} = 5.05 \times 10^{-2} (\text{mg/kg/d})^{-1}$$

2. adjustment for body weight and breathing rate of rats

$$[5.05 \times 10^{-2} \text{ (mg/kg/d)}^{-1} / .35 \text{ kg}] * .223 \text{ m}^3/\text{d} = 3.22 \times 10^{-2} \text{ (mg/m}^3\text{)}^{-1}$$

$$\text{or } 3.22 \times 10^{-5} \text{ (ug/m}^3\text{)}^{-1}$$

3. In this assessment EPA assumed that only 50% of the vinyl chloride was absorbed through the lungs. To correct for this the ql* value has't to be multiplied by .5.

$$(.5) * 3.22 \times 10^{-5} \text{ (ug/m}^3\text{)}^{-1} = 1.61 \times 10^{-5} \text{ (ug/m}^3\text{)}^{-1}$$

$$\text{or } 4.12 \times 10^{-2} \text{ ppm}^{-1}$$

The state of Mississippi is recommending a ql* value of $4.2 \times 10^{-5} \text{ (ug/m}^3\text{)}^{-1}$. This value is derived from the more recent EPA report just described from the ql* value of $2.95 \times 10^{-1} \text{ (mg/kg/d)}^{-1}$. As you can see this number is 2.6 fold greater than the number calculated above (1.61×10^{-5}). Mississippi derived their number as follows.

$$\begin{aligned} 1. \quad [2.95 \times 10^{-1} \text{ (mg/kg/d)}^{-1}] * (.5) * (20 \text{ m}^3/\text{d}) * (10\text{-}3 \text{ mg/ug}) / 70 \text{ kg} \\ = 4.21 \times 10^{-5} \text{ (ug/m}^3\text{)}^{-1} \end{aligned}$$

This calculation is wrong, since they did not back calculate to the original experimental air levels of vinyl chloride.

The Toxic Substances Control Program in the California Department of Health Services is currently recommending a unit risk of $7.14 \times 10^{-2} \text{ (mg/kg/d)}^{-1}$ (personal communication, Dr. John Brantner, staff toxicologist, California Department of Health Services). By using the same calculation procedure that Mississippi used and using California's assumption of 42% retention of vinyl chloride by the lungs, this converts to a ql* of $8.57 \times 10^{-6} \text{ (ug/m}^3\text{)}^{-1}$ (I was unable to get enough data to perform the correct calculations which would result in a lower ql*). The California Department of Health Services recommends this unit risk estimate to determine acceptable vinyl chloride levels at toxic waste sites. However, The California Air Resources Board is considering promulgating a ql* value of $20 \times 10^{-5} \text{ ppb}^{-1}$ ($7.81 \times 10^{-5} \text{ (ug/m}^3\text{)}^{-1}$). I do not have the information to determine which animal studies were used in this determination. However, the use of this value would result in the lowest acceptable ambient air concentration.

The following table provides the ql* values currently used by various states in setting ambient air concentrations considered to provide an acceptable cancer risk of 10^{-6} .

State	unit risk (ql*) (ug/mm ³) ⁻¹	acceptable exposure (cancer risk of 10^{-6})
-------	--	--

KS	$.26 \times 10^{-6}$	3.85 ug/m ³
KS-KC	4.1	.24
MA	2.6	.38
MI	2.5	.40
NC	2.6	.38
NY	2.5	.40
PA-Phil	0.16	6.25
TX	0.10	10.
VT	5.00	.20
EPA (old)	2.72	.37
EPA (new)	16.1	.06
CA (toxic Substances Control Program)	8.57	.11
CA (proposed by Air Resources Board)	78.1	.01
MS	42	.02

As you can see from this table many of the states are using EPA's old q1* value for determining levels not to exceed a cancer risk of 10^{-6} .

If one uses the new EPA q1* the acceptable levels would have to be reduced by a factor of 6 over the old estimates. In setting the new q1*, however, the data used looks very suspicious. For example, q1* was calculated using these data points from the rat inhalation studies;

transformed dose corrected for average dose amount absorbed	incidence (liver angiosarcoma) No. responding/No. tested or examined
0.344 mg/kg/day	1/119
0.860	5/120
1.719	1/60
3.438	1/120

As you can see there is no dose response relationship and by substituting these points into the statistical GLOBAL program to calculate a unit risk doesn't make sense. Toxicologists have raised several questions about the animal inhalation studies by Maltoni used in the EPA calculations and they may not be the appropriate studies to use. The EPA $q1^*$ values have not undergone any credible scientific peer review. The most recent document (EPA/600/x-85/374 September 1985) in which the most conservative $q1^*$ value of $16.1 \times 10^{-6} \text{ (ug/m}^3\text{)}^{-1}$ was obtained and used by the State of Mississippi is an external draft and the disclaimer states it does not constitute Agency Policy. However, the earlier EPA document (EPA/540/1-86-036, September 1984) which has the $q1^*$ value of $2.5 \times 10^{-2} \text{ (mg/kg/d)}^{-1}$ does not have this disclaimer, and therefore on policy grounds, should be the one that the Agency recommends using. However, even this number [$2.5 \times 10^{-2} \text{ (mg/kg/d)}^{-1}$] can be challenged because it has not undergone any public comment period or any official regulatory sign-off authority within the Agency.

The following arguments can be made to discard Mississippi's $q1^*$ value of $42 \times 10^{-6} \text{ (ug/m}^3\text{)}^{-1}$.

1. The calculation performed was on a $q1^*$ value that EPA has not officially endorsed. There is no $q1^*$ value given in the IRIS data base for vinyl chloride.
2. The conversion mg/kg/d to ug/m^3 that the Mississippi Department of Environmental Quality used was incorrect. The right conversion would decrease the $q1^*$ value by 2.6.
3. The data used in calculating the higher EPA $q1^*$ value is not of sufficient quality to determine a $q1^*$ value.
4. The Maltoni inhalation data used by EPA in both reports may not be of sufficient quality to perform a quantitative risk assessment for vinyl chloride.
5. YOU HAVE GOOD GROUNDS TO ARGUE FOR THE LOWER $q1^*$!

The bigger problem may lie in California and could affect other states if they adopt the Air Resources Board proposed $q1^*$ of $20 \times 10^{-5} \text{ ppb}^{-1}$. This could be addressed through public comments, and meetings, possibly through your company and/or the Vinyl Institute.