December 29, 2003

Mr. Jeffrey B. Margulies
Associate Executive Director
California Paint Council
1333 36th Street
Sacramento, California 95816

Dear Mr. Margulies:

On behalf of the Office of Environmental Health Hazard Assessment (OEHHA), I am pleased to inform you of our decision to grant the California Paint Council, on behalf of the National Paint and Coatings Association, a safe use determination for crystalline silica in interior flat latex paints containing 6% crystalline silica, or less, with diatomaceous earth as the sole source of crystalline silica, pursuant to our authority under Section 12204 of Title 22 of the California Code of Regulations.

Please find enclosed copies of our document supporting the determination and the notice, as it appears in the *California Regulatory Notice Registry*, dated December 26, 2003, and on the OEHHA website at www.oehha.ca.gov. If you would like to discuss any issue concerning the safe use determination further, please call me at (916) 324-7572

Sincerely,

[*Original signed by*]

George V. Alexeeff, Ph.D., D.A.B.T.
Deputy Director for Scientific Affairs

Enclosures

Supporting Materials for a Safe Use Determination
For Crystalline Silica in Interior Flat Latex Paint
Office of Environmental Health Hazard Assessment
December 2003

I. Introduction

On April 28, 2003, the Office of Environmental Health Hazard Assessment (OEHHA) convened a public hearing for comment on a request for a safe use determination for interior flat latex paint containing crystalline silica. Crystalline silica (airborne particles of respirable size) is on the Proposition 65 list of chemicals known to the state to cause cancer.

Specifically, the requester, the California Paint Council, on behalf of the National Paint and Coatings Association, has asked OEHHA to grant a safe use determination for exposure to particles of crystalline silica of respirable size that results from the normal use of interior flat latex paint. The products that are the subject of this request are interior flat latex paints that may contain "extender pigments," compounds added to paint to impart specific characteristics, in this case, a more flat (dull) sheen. These compounds may contain crystalline silica.

The requester submitted technical data and other technical information, which included the results of testing designed to assess the level of exposure to respirable crystalline silica during normal use of interior flat latex paint. This testing involved both sanding activity in preparation for painting as well as painting activity by airless spray guns, the method most likely to produce respirable aerosols of paint. Three other common methods of paint application, brushing, rolling, and sponging, are far less likely to produce respirable aerosols, and were not included in testing by the applicant.

The submission included statistics on the frequency and duration of painting activities.

OEHHA agreed to perform a screening level evaluation of this request for a safe use determination. In this approach, the focus is on exposure and a safe use determination would be issued should the exposure level, determined based on the testing data and several assumptions about frequency and duration of painting activity, fall below that which would produce an upper-bound cancer risk of one in 100,000 using conservative default cancer potency values readily available from the scientific literature.

The screening assessment has shown that the estimated exposure of the average user of interior flat latex paint to respirable crystalline silica, under the conditions described in this assessment, is unlikely to trigger a Proposition 65 warning requirement. A more detailed account of the screening assessment is described below.

II. Screening Level Exposure Assessment

A. Assumptions

The development of this screening level assessment required that a number of default assumptions be made. These assumptions have been adopted for the purpose of this screening assessment and may not constitute future OEHHA or Cal/EPA policy regarding crystalline silica and/or interior flat latex paint.

- Brushing, rolling, and sponging of latex paints generates very low amounts of respirable aerosol. Spraying is the only painting method that generates any amount of respirable aerosol.
- All crystalline silica in particles of respirable size is of concern regardless of whether the crystals are isolated or whether they are embedded/agglomerated with other material (paint).
- The measurements of respirable dust provided by NPCA are representative of paint products with identical crystalline silica content produced by NPCA member companies.
- The extender pigments described by NPCA – diatomaceous earth, air-floated clay, and talc – are the only components of paint that contain crystalline silica.
- The information provided by NPCA regarding the characteristics of extender pigments which have the potential to contain crystalline silica are representative of those used in commercially available paints.
- The enclosed-chamber exposure studies conducted by NPCA are appropriate for the evaluation of respirable dusts to which the average user of interior flat latex paint may be exposed.
- The testing conditions used by NPCA, particularly with respect to temperature and humidity, are representative of the conditions encountered by the average user of interior flat latex paints. Further, the range of changes in these parameters expected to be encountered by such users are assumed not to significantly alter the exposure to latex paint aerosols or sanded dusts.
- The actual duration and frequency of painting/sanding activities by average users of interior flat latex paint are similar to or less than the estimates provided by NPCA.
- Painting activity is constant throughout the average user's lifetime (year-to-year painting activity is constant, with the same formulation of paint).

B. Latex Paint Exposure Scenario and Estimate

The primary exposures to respirable crystalline silica from the normal use of interior flat latex paint occur as a result of the painting activity itself (whether from brushing, rolling, or spraying) and sanding activity in preparation for re-painting. OEHHA has not identified any other activities involving the normal use of latex paint that are likely to result in significant exposure to respirable crystalline silica.

The following algorithm has been used to estimate exposure to respirable crystalline silica from the average use of interior flat latex paint:

Total exposure = [exposure from painting activity]
+ [exposure from sanding in preparation for re-painting]

For both painting and sanding activities, NPCA has provided testing data for three formulations of paint containing different amounts of crystalline silica. These were not commercially available paints, but paints formulated to contain specific quantities of crystalline silica representing the range of crystalline silica content in interior flat latex paints generally in use. The source of crystalline silica in the formulations tested by NPCA was diatomaceous earth (Celite 281®, median particle size 12.45 µm). The crystalline silica content in these test formulations was 0.1% (Formula A), 0.5% (Formula B), or 6% (Formula C). Interior flat latex paints with higher levels of crystalline silica content (*e.g.*, 12%) are also available, and there is an absence of information on the median particle size of crystalline silica in commercially available paints.

Exposure from painting activity

The testing strategy employed real-time measurement of total aerosol levels in the breathing zone of individuals engaged in painting activity in a poorly ventilated room. Each individual wore five sampling pumps. The test rooms (two rooms: 10 feet wide, 12 feet long, and eight feet high) were supplied by a dedicated ventilation system with 0.5 air changes per hour and the individuals were engaged in painting activity for periods of eight hours. Painting was performed on butch-block paper to facilitate continuous painting activity. Breathing zone samples were collected on polyvinylchloride filters in accordance with American Conference of Governmental Industrial Hygienists (ACGIH) and National Institute of Occupational Safety and Health (NIOSH Method 0600) methods. Crystalline silica was measured on pooled filters by X-ray diffraction in accordance with NIOSH Method 7500.

Testing on three separate days for each type of paint in the closed chamber produced the following levels of respirable aerosol and is presented in Table 1 below.

Table 1. Average daily exposure to <u>total</u> respirable aerosol from the spraying of formulations of paint containing three different levels of crystalline silica.

Paint Type (% Crystalline Silica)	Day	Average Daily Exposure (mg/m^3) [a]
Formula A (0.1%)	1	4.30
	2	4.59
	3	4.82
Formula B (0.5%)	1	5.14
	2	4.24
	3	3.88
Formula C (6%)	1	2.78
	2	1.79
	3	1.45

[a] Three 8-hour painting days were performed using a airless spray gun. Exposure was calculated based on the mean of 3-5 samples on each day.

Measurement of crystalline silica content of respirable aerosols from these samples showed no detection of crystalline silica above the method's detection limit, which ranged from 6.8 to 20.3 $\mu g/m^3$. Based on theoretical calculation of crystalline silica content of respirable paint aerosol, assuming homogeneous dispersal of the crystalline silica in all aerosol particles, crystalline silica exposure would have been expected to be 4-5 $\mu g/m^3$ for Formula A, 19-26 $\mu g/m^3$ for Formula B, and 87-167 $\mu g/m^3$ for Formula C [as calculated by NPCA], levels which, at least in the case of Formulas B and C, should have been detectable in the filters. The applicant states that the basis for the discrepancy between the measured amounts (non-detects) and the theoretical values is a physical property of the diatomaceous earth in the paint formulations, namely the median particle size of 12.45 µm. Most of the crystalline silica particles in the paints were above respirable size (10 µm) and partitioned out of the respirable paint aerosol when the aerosol was generated. This is the likely reason for the lack of crystalline silica detection in respirable wet paint aerosol under these testing conditions (See also Section V. Scope of Interior Flat Latex Paints Covered by This Safe Use Determination). Given that liquid paint will likely coat all particles of diatomaceous earth in paint spray, the diatomaceous earth particle diameter would need to be considerably less than 10 µm for a substantial fraction of crystalline silica to occur in respirable wet paint aerosol.

NPCA has provided estimates of workload factors (*i.e.*, estimates of duration and frequency of painting and sanding activities) for professional painters engaged in painting activity. For professional painters, the average time spraying interior paints was five hours per task, 81 days per year, for an annual average of 405 hours. For homeowners doing their own painting, spraying was much less likely to be done, since homeowners generally use either brushes or rollers to apply paint, methods unlikely to generate significant amounts of respirable paint aerosol. Therefore estimates of exposure to homeowners from spraying (as well as rolling and brushing) were considered negligible. OEHHA agrees that these are reasonable estimates for average activity times, and that disregarding the homeowner painting activity does not compromise the worst-case estimates provided in the application.

Exposure from sanding activity

Sanding was performed on painted walls (*vs.* butcher block paper) in the same enclosed rooms used for the sampling from the painting activity. The individual performing the activity lightly sanded the entire room (average time: 14 to 34 minutes), before moving to the second room. While the second room was sanded the first room was flushed and vacuumed to remove residual paint dust, permitting the first room to be re-sanded. Activity continued for eight hours. Dust samples from the breathing zone were collected by Personal DataRAM and ultimately analyzed as similarly to the paint aerosol samples.

Testing on six separate days in the closed chamber produced the following levels of respirable paint dust, presented in Table 2 below.

Table 2. Average daily exposure to total respirable dust from the sanding of formulations of paint containing three different levels of crystalline silica.

Paint Type (% Crystalline Silica)	Day	User [a]	Average Daily Exposure (mg/m^3) [b]
Formula A (0.1%)	1	Homeowner	<0.01
	2	Homeowner	<0.02
	3	Professional	<0.01
	4	Homeowner	<0.02
	5	Professional	<0.01
	6	Professional	<0.01
Formula B (0.5%)	1	Homeowner	<0.01
	2	Homeowner	0.01
	3	Homeowner	<0.01
	4	Professional	<0.01
	5	Professional	0.02
	6	Professional	<0.01
Formula C (6%)	1	Homeowner	0.06
	2	Professional	0.15
	3	Professional	0.13
	4	Professional	0.13
	5	Homeowner	0.08
	6	Homeowner	0.05

[a] "Homeowner" sanding indicates three 6-hour sanding days using a 3"×6" curved rubber sanding block; "professional" sanding indicates three 8-hour sanding days using a 4"×9" hand sander with grip or a pole sander.
[b] Average daily exposure to respirable dust, representing exposure during time engaged in paint sanding activity.

NPCA has provided estimates of workload factors for both professional painters and homeowners engaged in interior sanding activity. For professional painters, the average time sanding interior paints in preparation for re-painting was two hours per task, 250 days per year, for an annual average of 500 hours. For homeowners, the average time sanding interior paints was 2.4 hours per task, 4.2 days per year, for an annual average of 10 hours.

Annual average respirable crystalline silica exposures by activity

NPCA has estimated annual average exposures to crystalline silica based upon the exposure studies described above and the assumptions regarding annual hours engaged in painting and sanding activity. Since sanding was the only activity for which measurable crystalline silica was detected, this activity is the only one for which the exposure estimates are certain. In the case of exposures from spraying interior flat latex paint containing 0.1, 0.5, or 6% crystalline silica as Celite 281 (median particle size, 12.45 µm), calculated and estimated exposures are based upon the limit of detection of crystalline silica. Thus, these estimates reflect an upper bound on anticipated exposures. These results are presented in Table 3 below. Clearly, the combination of painting and sanding by professionals with the paint with the highest crystalline silica content presents the greatest threat of exposure to crystalline silica.

Table 3. Potential Annual Respirable Crystalline Silica Exposures.

Work Activity	Exposure Group (Annual Hours)	Paint Formula (% Crystalline Silica)	Calculated Hourly Respirable Crystalline Silica During Activity (µg/m^3)	Estimated Annual Average Respirable Crystalline Silica Exposure (µg/m^3)
Painting	Professionals (405 hrs.)	A (0.1%)	6.8	0.31
		B (0.5%)	8.2	0.38
		C (6%)	8.8	0.41
Sanding	Professionals (500 hrs.)	A (0.1%)	0.001	0.000057
		B (0.5%)	0.04	0.0023
		C (6%)	10.1	0.58
	Homeowners (10 hrs.)	A (0.1%)	0.007	0.000008
		B (0.5%)	0.04	0.000046
		C (6%)	4	0.0046

C. Conditions Which May Affect Exposure Estimates

In the development of this screening assessment of exposure to respirable crystalline silica, a heavy reliance was made upon statistics provided by NPCA concerning the "normal" use of interior flat latex paint. The assessment of exposure required certain assumptions and testing conditions which may have led to over- or under-estimates of exposure to crystalline silica. We have tried to identify some of the factors which may influence the estimates, and where possible identify the contribution they may make to human exposure.

Conditions/factors which would tend to produce over-estimates of exposure:

- Open room factor; testing was performed in poorly ventilated room. Many rooms, though not all, painted by the average user will be better ventilated than the test room.
- Exposure times less than those used in this assessment, notably including a lower likelihood that interior flat latex paint will be sanded prior to painting (flat paints generally do not require significant sanding to provide good coverage/adhesion for the next coat).

- Alleged clumping of diatomaceous earth particles in paint matrix, reducing respirable fraction.

Conditions/factors which would tend to produce under-estimates of exposure:

- Substantial fraction of crystalline silica content less than 10 μm diameter (from any source).
- Sanding of someone's residence may expose residents to indoor air containing respirable crystalline silica after sanding activity has ceased.

III. Readily Available Estimates of the Cancer Potency of Crystalline Silica

Numerous reviews exist concerning the carcinogenicity of crystalline silica. Epidemiological studies of human populations exposed to crystalline silica, primarily in occupational settings, have shown evidence for the development of lung tumors. The studies have also provided some estimates of exposure levels. While the studies are limited in many respects, they have provided data from which extrapolated risks can be drawn. Epidemiological studies from which risk estimates have been drawn include studies of South African gold miners by Hnizdo and Sluis-Cremer (1991) and California diatomaceous earth workers by Checkoway *et al.* (1993), both of which showed a dose-response relationship between the silica exposure and the development of lung cancer (reviewed in Goldsmith *et al.*, 1995). Risks were estimated based on the number of person-years at risk for a given dust exposure level. The Global 86 model was fit to the data points and adjustments were made for occupational exposure (40 year employment; 8 hour workshifts; 50 hour workweek; 50 workweeks per year). Cancer slope factors derived from these studies ranged from 6.8×10^{-7} to 1.85×10^{-5} for continuous (24-hr, lifetime) exposure to 1 $\mu g/m^3$ silica dust (Goldsmith *et al.*, 1995). Based on these estimates, concentrations associated with a risk of one in 100,000 would range from 0.54 to 15 $\mu g/m^3$ silica dust.

We acknowledge that the body of evidence regarding the carcinogenicity of crystalline silica is evolving. In particular, recent work has focused on the relationship between the development of silicosis and lung cancer in humans and on the nature of the contribution of reactive oxygen species to the development of malignancy. It has also been recognized in the scientific literature that the "biological activity" of crystalline silica may vary depending on the exposure scenario (freshly fractured *vs.* aged particle surfaces). A full consideration of these factors is beyond the scope of this screening assessment; however, a recognition of these concerns would likely lead to reductions in the estimation of the cancer-causing potential of the crystalline silica contained in the sorptive materials used in latex paint. Thus, we expect that the screening potency estimates presented above represent "worst case" estimates of the true potency for crystalline silica present in latex paint.

Cancer risk from exposure to respirable crystalline silica is expected to vary with breathing rate, with increased breathing rate associated with increased internal dose and thus also cancer risk. Although no information is available regarding the breathing rates of consumers engaged in latex paint use, it is not anticipated that the breathing rate of the average user, during the course of painting activity, would be significantly greater than that of the workers from which the cancer slopes were derived.

IV. Discussion of Respirable Crystalline Silica Exposure Levels from Use of Interior Flat Latex Paints Relative to Cancer Potency Estimates

Estimates developed from the exposure data provided by NPCA indicate that yearly average exposure levels to respirable crystalline silica from the normal use of interior flat latex paints (painting plus sanding) range from 0.31 µg/m^3 for paint containing low levels of crystalline silica (0.1%) to 0.99 µg/m^3 for paints with higher levels of crystalline silica (6%). With the assumption that an individual uses a single product throughout his/her lifetime, the highest estimate produced is an annual time weighted average exposure of 0.99 µg/m^3 respirable crystalline silica. This exposure level is approximately two-fold higher than the lowest concentration (0.54 µg/m^3) associated with a risk of one in 100,000 persons exposed derived from occupational epidemiological studies. With this said, however, a substantial fraction (~40%) is based on theoretically calculated exposures under circumstances in which no crystalline silica was detected in the sampling scenario. Further, there is some illogicality to the observation that with paint aerosol exposures, there is no observed relationship between the exposure levels to crystalline silica calculated on the basis of the limit of detection by the test method (*vs.* measured crystalline silica) and measurable content of crystalline silica in the starting material (0.1%, 0.5%, and 6% crystalline silica paints resulting in theoretical annual average exposures of 0.31, 0.38, and 0.41 µg/m^3). Since NPCA took a reasonable approach in its effort to measure crystalline silica from the spraying activity, *i.e.*, the pooling of filters, OEHHA believes the wet aerosol portion of the exposure may be much less toxicologically significant than that produced from the dusts that result from sanding. In the screening level analysis, the annual average exposure levels from sanding were 0.58 µg/m^3 crystalline silica, very close to the lower limit of the screening benchmark range. Given the uncertainties in the estimated crystalline silica exposure level from sanding activity and the effort in the exposure testing to produce an estimate based on a scenario weighted toward exposures resulting from the high end of normal use (both in terms of using a poorly ventilated room and a high frequency of painting activity), this estimate is not substantially different from the screening benchmark.

Because in this screening assessment the exposure concentrations approximated those associated with no significant cancer risk, it was not necessary to resolve further technical issues surrounding the upper bound estimates of cancer slope provided in the literature (*i.e.*, by Goldsmith *et al.*, 1995). Thus, based on the assumptions made above, the estimated exposure to respirable crystalline silica as a result of the normal use of interior flat latex paint containing *less than* 6% crystalline silica corresponds to an excess cancer risk of less than one in 100,000, and would not trigger the Proposition 65 warning requirement.

V. Scope of Interior Flat Latex Paints Covered by This Safe Use Determination

NPCA has provided exposure assessment data for three paints containing Celite 281 (median particle size, 12.45 µm), a diatomaceous earth, as a flattening agent. As stated in the application materials, diatomaceous earth, talcs, and clays with high oil absorption coefficients (so-called extender pigments), all of which may contain crystalline silica, are added to interior flat latex paints. Synthetic amorphous silica is also added to paints, but it does not contain crystalline silica, so will not be discussed further. NPCA has provided specification sheets with characteristics of several diatomaceous earth, air-floated clay, and talc products used as extender pigments. Those that contained crystalline silica, and thus of concern under Proposition 65, are summarized in Table 4 below.

Table 4. Extender pigments containing crystalline silica used in interior flat latex paints and select characteristics.

Extender Pigment	Number of Products	% Crystalline Silica	Median Particle Size
Diatomaceous earth	9	<2 to 72.5%	8.5 to 14.5 µm
Air-floated clay	13	<0.1 to <1%	0.2 to 4.5 µm
Talc	4	0.15 to <1%	7.0 to 8.7 µm

Based on this information, diatomaceous earth appears to have the greatest potential to be a significant source of exposure to crystalline silica from the normal use of interior flat latex paints because of the relatively high fraction of crystalline silica in the products (up to ~72% *vs.* <1% for talcs and air-floated clays). Although NPCA did not provide data on the relative quantities of each of these ingredients in paint formulations, 6% crystalline silica paint cannot be produced using solely an ingredient that contains <1% crystalline silica. The median particle size of diatomaceous earth products containing crystalline silica ranged from 8.5 to 14.5 µm. Since these products are constituted of particles with a median particle diameter near or greater than respirable size, exposures occurring from the spraying of paint aerosols are likely to be minimal, given the coating of the particles with the water and other wet latex paint ingredients, even diatomaceous earth particles slightly smaller than respirable size are not likely to be "respirable" when aerosols are generated as wet paint. On the other hand, sanding is likely to result in the fracturing of larger particles to ones of respirable size, so diatomaceous earth remains a concern as a component of paint and the exposures to crystalline silica that result from the sanding of this paint.

Twenty-one air-floated clay products were described, thirteen of which may contain some amount of crystalline silica that ranged from "<0.1%" to "<1%". Three products had defined fractions of crystalline silica: 0.35, 0.14, and 0.14%. Of those that contained crystalline silica, the median particle diameters ranged from 0.2 to 4.5 µm. Because of the relatively small particle diameters of air-floated clays, the potential for them to occur in respirable wet aerosols of latex paints appears to be considerably greater than for diatomaceous earth products. For this reason, and because no testing data were available for paints containing this ingredient, OEHHA cannot make conclusions regarding exposure to paints with this source of crystalline silica. Therefore, interior flat latex paints containing air-floated clay as a contributor to the crystalline silica content are not covered by this safe use determination.

Eight talc products were described, four of which may contain some amount of crystalline silica that ranged from 0.15 to 1% of the product (a single product was described as "<1%" crystalline silica). Of those that contained crystalline silica, the median particle diameters ranged from 7.0 to 8.7 µm, intermediate between diameters indicated for diatomaceous earth and air-floated clay products. As with air-floated clay products, no testing data were available for paints containing this ingredient. Given the uncertainty regarding the potential for particles of this size to occur in wet paint aerosols, OEHHA cannot rule out the possibility that exposures to crystalline silica at levels above the benchmark described above will occur. Therefore, interior flat latex paints containing talc products as a source of crystalline silica are not covered by this safe use determination.

NPCA has provided exposure assessment data for three formulations of paints it considers representative of the interior flat latex paints in common use, with the paint containing 6% crystalline silica at the high end of the range. NPCA has stated that approximately 25% of paints sold will contain between a trace (0.1-0.5%) and 6% crystalline silica. Approximately 2% will be above 6% crystalline silica and 23% will be below 0.5% crystalline silica. Since OEHHA has identified a few interior flat latex paints that contain higher amounts of crystalline silica, and since no testing data are available for such paints, OEHHA must restrict the safe use determination to paints containing *6% crystalline silica, or less, with diatomaceous earth as the sole source*.

VI. References

Checkoway H, Heyer NJ, Demers PA, Breslow NE (1993). Mortality among workers in the diatomaceous earth industry. Br J Ind Med 50:586-97.

Goldsmith DF, Ruble RP, Klein CO (1995). Comparative cancer potency for silica from extrapolations of human and animal findings. Scand J Work Environ Health 21(Suppl 2):104-7.

Hnizdo E, Sluis-Cremer GK (1991). Silica exposures, silicosis, and lung cancer: a mortality study of South African gold miners. Br J Ind Med 48:53-60.