CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)

NOTICE TO INTERESTED PARTIES
DECEMBER 26, 2003

ISSUANCE OF A SAFE USE DETERMINATION FOR CRYSTALLINE SILICA IN INTERIOR FLAT LATEX PAINT

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA), as the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), has received a request from the California Paint Council, on behalf of the National Paint and Coatings Association (NPCA), that OEHHA grant a safe use determination for interior flat latex paint containing crystalline silica, pursuant to its authority under Section 12204 of Title 22 of the California Code of Regulations (CCR). The products that are the subject of the request are interior flat latex paints that are used by homeowners, professional painters, and other consumers. Crystalline silica (airborne particles of respirable size) has been listed under Proposition 65 as a chemical known to the State to cause cancer since October 1, 1988.

In accordance with the process set forth in 22 CCR, Section 12204(f), public comment on this request was solicited on March 28, 2003, particularly with respect to the potential for exposure to airborne particles of crystalline silica of respirable size that may result from the use of interior flat latex paints. A public hearing was convened on the last day of the 30-day comment period, April 28, 2003, in Sacramento, California.

Based on the results of a screening level assessment using testing data submitted by NPCA on the amounts of respirable crystalline silica produced from the normal use of interior flat latex paints, OEHHA has decided to issue a safe use determination to NPCA for crystalline silica in *interior flat latex paints containing 6% crystalline silica, or less, with diatomaceous earth as the sole source of crystalline silica*. The essential elements and results of this screening level assessment are described below.

Painting with an airless spray gun and sanding in preparation for re-painting were the activities determined to produce the greatest opportunity for exposure to airborne particles of respirable size. For painting, 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. Sanding was performed on painted walls in the same enclosed rooms used for the sampling from the painting activity. For both painting and sanding activities, NPCA provided testing data for three formulations of paint containing different amounts of crystalline silica. These were not commercially available paints, but paints formulated by NPCA 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, 0.5, or 6%. 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. Data provided by the requester also included statistics on the frequency and duration of painting and sanding activities by the average user (both homeowners and professional painters). In accordance with the process set forth in 22 CCR, Section 12204(f), OEHHA has previously deemed the submitted data adequate and appropriate for performing this screening level assessment.

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 $\mu g/m^3$ for paint containing low levels of crystalline silica (0.1%) to 0.99 $\mu g/m^3$ 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 $\mu g/m^3$ respirable crystalline silica. With this said, however, a substantial fraction (~40%, up to 0.41 $\mu g/m^3$) is based on theoretically calculated exposures (based upon the limit of detection) under circumstances in which no crystalline silica was detected in the sampling scenario. NPCA states that the basis for the lack of detectable crystalline silica in the respirable paint aerosol 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. 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. Excluding the wet aerosol portion of the exposure estimate results in annual average exposure levels from sanding of 0.58 $\mu g/m^3$ crystalline silica for the paint with the highest concentration of crystalline silica, which is an upper bound estimate.

A number of factors may tend to increase or decrease estimates of exposure relative to the approach used to develop the exposure levels described above. We believe, on the whole, that the assumptions made are likely to have resulted in overestimates of exposure levels from the average use of interior flat latex paint.

For the estimation of risk of cancer from the exposure to crystalline silica, readily available potency estimates in the scientific literature were used. Estimates derived from epidemiological studies were considered to be most appropriate for this screening evaluation of carcinogenic risk. Goldsmith *et al.* (1995; Scand J Work Environ Health 21(Suppl 2):104-7) has developed estimates of risk based upon the increase in lung cancers observed in epidemiological studies of gold miners in South Africa and diatomaceous earth workers in California. Cancer slope factors derived from these studies ranged from 6.8×10^{-7} to 1.85×10^{-5} for exposure to 1 $\mu g/m^3$ silica dust and were derived using occupational exposure assumptions of 40 years of employment, eight hour workshifts, 50 hour workweeks, and 50 workweeks per year. Based on these estimates, concentrations associated with excess cancer risk of one in 100,000 would range from 0.54 to 15 $\mu g/m^3$ silica dust. Active research is being conducted with respect to the relationship

between silicosis and lung cancer in humans, the contribution of reactive oxygen species to the development of malignancy, and the "biological activity" of crystalline silica. Additional data and increased confidence in information regarding crystalline silica's mode of action in the induction of human malignancy will likely lead to reductions in cancer potency estimates. Thus we expect that the upper end of the screening cancer slope factors presented above represent a "worst case" estimate of the true low dose cancer slope factor for crystalline silica present in interior flat latex paint.

The annual average exposure level of 0.58 $\mu g/m^3$ crystalline silica from sanding is 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 duration of sanding activity), this estimate is not substantially different from the screening benchmark.

Components of interior flat latex paint other than diatomaceous earth may be sources of crystalline silica, namely air-floated clays and talcs. Because of the relatively smaller particle diameters of these components, the potential for them to occur in respirable wet aerosols of interior flat 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 these ingredients, OEHHA cannot make conclusions regarding the exposure to paints with these sources of crystalline silica. Therefore, interior flat latex paints containing air-floated clays and talcs as contributors to the crystalline silica content are not covered by this safe use determination.

As provided in 22 CCR, Section 12204 (a) and (k), this safe use determination is specific to the requester, the California Paint Council, on behalf of the National Paint and Coatings Association, and for crystalline silica exposures in *interior flat latex paints containing 6% crystalline silica, or less, with diatomaceous earth as the sole source of crystalline silica*, as used in accordance with the facts presented in the request, and is advisory only. Moreover, the issuance of a safe use determination does not affect the authority of the Attorney General, district attorneys, certain city attorneys and any other person in the public interest to prosecute violations of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) pursuant to Health and Safety Code Section 25249.7 nor does it affect the responsibility of courts to interpret the Act and apply the provisions of the Act to particular facts.

Questions regarding this notice should be directed to:

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