May 20, 1999

Mr. S. Lee Coogan
Executive Director
Sorptive Minerals Institute
818 Connecticut Avenue, NW
Washington, District of Columbia 20006

Dear Mr. Coogan:

On behalf of the Office of Environmental Health Hazard Assessment, I am pleased to inform you of our decision to grant the Sorptive Minerals Institute a safe use determination for crystalline silica in packaged sorptive mineral-based pet litter, pursuant to our authority under Section 12104 of Title 22 of the California Code of Regulations.

Please find enclosed a copy of the notice, as it will appear in the *California Regulatory Notice Registry*, on June 4, 1999. 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

Enclosure

cc: Laurie E. Nelson
Randlett/Nelson Associates
1110 Second Street
Sacramento, California 95814

GVA:ke

Supporting Materials for a Safe Use Determination
for Crystalline Silica in Sorptive Mineral-Based Pet Litter
Office of Environmental Health Hazard Assessment
May, 1999

I. Introduction

On July 17, 1998, a request was made to the Office of Environmental Health Hazard Assessment (OEHHA) for a safe use determination for packaged sorptive mineral-based pet litter containing crystalline silica. Crystalline silica is on the Proposition 65 list of chemicals known to the state to cause cancer and its listing is limited to exposures to airborne particles of respirable size.

Specifically, the requester, the Sorptive Minerals Institute (SMI), has asked OEHHA to grant a safe use determination for the normal use of sorptive mineral-based pet litter (both "conventional" and "scoopable" types) and the exposure to particles of crystalline silica of respirable size that results from this use. The products that are the subject of this request are clay-based pet litters that are purchased and poured by the consumer, used by the pet, disposed of by the consumer, and replenished by the consumer.

The requester submitted several sets of technical data and other technical information which included the results of exposure assessment testing designed to replicate the level of consumer exposure to crystalline silica during normal use of pet litter. These studies were designed to measure the degree of exposure to respirable quartz dust generated from the normal use of both conventional and scoopable pet litters.

The submission included statistics on normal use of pet litter in terms of time and amount used.

The following tiered approach to the evaluation of this request for a safe use determination has been previously outlined to the requester. The first tier consisted of a "screening level" assessment with an initial focus on exposure. A screening level safe use determination would be issued should the exposure level determined based on the testing data fall below that which would produce an upper-bound cancer risk below one in 100,000 using conservative default cancer potency values already available. The requester has submitted testing data on the amounts of respirable crystalline silica produced from the normal use of conventional and scoopable pet litter. Should the screening level assessment using conservative assumptions fail to demonstrate safe use, a fuller assessment of the cancer risks associated with the use of clay-based pet litters would be undertaken. The screening assessment has shown that the estimated exposure of the average user of either conventional or scoopable pet litter to respirable crystalline silica under the conditions described in this assessment would not trigger the Proposition 65 warning requirement, thus the fuller assessment was not performed. A more detailed account of the screening assessment is described below.

II. 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 pet litter.

- As described by SMI, the only form of crystalline silica of concern in sorptive mineral-based pet litters produced by SMI member companies is quartz
- All quartz in particles of respirable size are of concern regardless of whether the crystals are isolated or whether they are embedded/agglomerated with other material (clay)
- The measurements of respirable dust provided by SMI are representative of pet litter products produced by SMI member companies
- The estimates of average pet litter consumption and use practices follow the parameters provided by SMI (except as indicated in this assessment)
- The experimental set-up described by SMI is appropriate for the evaluation of respirable dusts to which the average user of pet litter may be exposed.
- The estimates of quartz content in pet litter sources from various geographic locations are representative of pet litter products
- Pet ownership and litter use is constant throughout the consumer's lifetime (single pet, same type litter)
- Dust produced from the pouring of pet litter is directly proportional to the amount poured
- Pet urine and water produce the same quality of scoopable clumps in pet litter in terms of dust generated from scooping activity

B. Conventional pet litter exposure scenario and estimate

The primary sources of exposure to dust containing crystalline silica from the use of conventional pet litter are from the filling of the litter pan and the subsequent disposal following use. The following algorithm has been used to estimate exposure to respirable quartz dusts from the average use of conventional pet litter:

Total exposure = [exposure from filling/pouring] + [exposure from disposal]

<u>Exposure from pouring of conventional pet litter</u>
SMI has provided information that the average consumer of conventional pet litter uses 326.4 pounds of pet litter per year and that the average time between changes of pet litter is 8.2 days. Assuming that all use of conventional pet litter is from the pouring and/or replacement activity, the average amount of pet litter poured and disposed of each time is 7.3 pounds and this activity is done 44.5 times per year. SMI has conducted 10 pound pour tests which provide data showing respirable dust estimates with measurements taken every 10 seconds over 3 minutes following the pouring. While SMI provided an estimate of 15 seconds for an average user to fill / pour the litter, calculations of the exposure to the dust were taken from the entire time span measured.

While the pouring itself may only take 15 seconds, the user may remain in the vicinity of the litter pan beyond that time (because of other related or unrelated activities). Since dust levels generally decline substantially to near background levels within 3 minutes (the exception being litter #3 which tailed off somewhat, but did not decline to near background), using this as the exposure time should overestimate dust exposure from filling / pouring.

The levels of respirable dust generated from the use of the products evaluated by SMI indicates that the range of the 3-minute time weighted average (TWA) exposure for the 12 products is 19 to 639 $\mu g/m^3$ in the 10-pound pour test. Using SMI's measured quartz concentration for each of the conventional litter products (range: 1.0 to 11.8% quartz), the range of 3-minute TWA quartz concentrations from respirable dust is 1.5 to 19.1 $\mu g/m^3$. These values were then adjusted to produce an estimate for average use (weight scaled to 7.3 pounds), time adjusted to a 24-hour TWA (1440 minute), and the exposure scaled for intermittent use (44.5 times per year). These exposure estimates for each of the conventional litter products ranged from **0.00037** to **0.0048 $\mu g/m^3$** respirable quartz.

Exposure from disposal of conventional pet litter

For purposes of this assessment, disposal was taken to be equivalent to initial pouring. SMI has proposed that disposal presents little opportunity for exposure to respirable particles because the product is dumped directly into a waste container or trash bag. We would counter that disposal will still produce dust and, depending upon the method / technique of disposal, there is the opportunity for exposure up to the equivalence of the initial pouring into the litter pan.

Thus, it is expected that the lifetime average exposure to respirable quartz from normal use of conventional pet litter (*i.e.*, filling/pouring and disposal) would be up to two-fold that observed in the pouring scenario, that is, in the range of **0.0007** to **0.01 $\mu g/m^3$**.

C. Scoopable pet litter exposure scenario and estimate

The following algorithm has been used to estimate the exposure to crystalline silica from the normal use of scoopable pet litter:

Total exposure = [exposure from initial pouring] +
[exposure from clump removal] +
[exposure from clump removal/replenishment] +
[exposure from disposal]

Exposure from initial pouring of scoopable pet litter

SMI has provided information that the average consumer of scoopable pet litter uses 176.4 pounds of pet litter per year and that the average time between complete changes of pet litter is 28.3 days. SMI did not provide estimates of the proportion of scoopable pet litter which is scooped out of the pan (versus that which is dumped with the complete change) relative to the total use, although testing data were provided showing weekly replenishment with one half pound of litter. If this is a reasonable estimate of the amount removed, annual totals for removal would be 26 pounds. This leaves approximately 150 pounds for the "monthly" filling/disposing

activities, or approximately 11.6 pounds per change. Thus, we felt that filling with 11.6 pounds of litter was a reasonable estimate. Thus, for the purpose of this exposure screen, the average amount of pet litter poured and disposed of each time was estimated at 11.6 pounds and this activity is done 12.9 times per year. SMI has conducted 10 pound pour tests which provide data showing average respirable dust levels with measurements taken every 10 seconds up to 140 seconds following the pouring. While SMI provided an estimate of 15 seconds for an average user to fill/pour the litter, calculations of the exposure to the dust were based upon data for the entire time span measured. While the pouring itself may only take 15 seconds, the user may remain in the vicinity of the litter pan beyond that time (because of other related or unrelated activities). Since dust levels generally declined substantially to near background levels within the time measurements were made (140 seconds), using this as the exposure time should overestimate dust exposure from initial filling / pouring.

The levels of respirable dust generated from the use of the products evaluated by SMI indicates that the range of the 140-second time weighted average (TWA) exposure for the nine products is 27.3 to 196 $\mu g/m^3$ in the 10-pound pour test. Using SMI's measured quartz concentration for each of the scoopable litter products in this test (range: 4.7 to 22.0 % quartz) and adjustment for average amount used (11.6 pounds), the range of 140-second TWA quartz concentrations from respirable dust is 1.6 to 30.3 $\mu g/m^3$. These values were then adjusted to a 24-hour TWA (1440 minutes), and the exposure scaled for intermittent use (12.9 times per year). These exposure estimates for each of the scoopable litter products ranged from **0.000092** to **0.0017 $\mu g/m^3$** respirable quartz.

<u>Exposure from scooping/replenishing of scoopable pet litter</u>
SMI has provided data from the measurement of respirable dust produced from the scooping and replenishing activities associated with the use of scoopable pet litter. The data provided included separate tests of scooping alone and scooping plus replenishment of litter. In these tests, the assumption was made that the average pet uses the litter box five times per day and that each use introduces 15 milliliters of fluid into the box. Scooping is performed once per day and was estimated by SMI to take 30 seconds. Scooping with replenishment of 0.5 pound of litter is performed once per week and was estimated by SMI to take 10 seconds per week. In the tests, dust measurements were made every 10 seconds for up to 140 seconds following either the clump removal or clump removal/replenishment activity. As was the case with the tests for the initial filling, the total time of measurement was used in our estimates of exposure since the user may remain in the vicinity of the litter pan beyond the time it takes to perform the activity. The dust levels tended to decline substantially before 140 seconds in these tests.
For the estimation of the quartz exposure from clump removal activity, the time-weighted average dust level was calculated for the 140 second test period for all nine products (range: 48 to 519 $\mu g/m^3$ total dust) and then adjusted for quartz content (1.2 to 13.9%) producing quartz exposure estimates ranging from 0.8 to 36.3 $\mu g/m^3$ quartz dust. These values were then adjusted for yearly exposure based on a 24-hour TWA (1440 minutes) and clump removal on six of seven week days (the other day being clump removal plus replenishment). Total annual average exposure for scooping activity was thus calculated to range from **0.0011** to **0.050 $\mu g/m^3$** quartz dust. This range was skewed by a seemingly aberrant measurement at the first 10 second reading for a single product (#15) of 2349 $\mu g/m^3$ total dust. If this product were disregarded because of

this measurement, the product with the highest annual quartz exposure estimate would be 0.028 $\mu g/m^3$.

For the estimation of the quartz exposure from clump removal with replenishment activity, the time-weighted average dust level was calculated for the 140 second test period for all nine products (range: 62 to 1313 $\mu g/m^3$ total dust) and then adjusted for quartz content (1.9 to 18.4%) producing quartz exposure estimates ranging from 2.3 to 35.5 $\mu g/m^3$ quartz dust. These values were then adjusted for yearly exposure based on a 24-hour TWA (1440 minutes) and clump removal/replenishment activity on one of seven week days. Replenishment with 0.5 pounds of litter seemed a reasonable estimate and thus no proportional adjustment was made (for a volume greater or less than 0.5 pound). Total annual average exposure from scooping/replenishment activity was thus calculated to range from **0.00053** to **0.0058 $\mu g/m^3$** quartz dust.

Exposure from disposal of scoopable pet litter

For purposes of this assessment, disposal was taken to be equivalent to initial pouring. SMI has proposed that disposal presents little opportunity for exposure to respirable particles because the product is dumped directly into a waste container or trash bag. We would counter that disposal will still produce dust and, depending upon the method / technique of disposal, there is the opportunity for exposure up to the equivalence of the initial pouring into the litter pan.

Total exposure from the use of scoopable pet litter

Total exposure was estimated for each product based on the sum of exposures from the various activities. Total exposure from all four activities (initial filling, disposal, clump removal, clump removal/replenishment) produced estimates for each product which ranged from **0.0018** to **0.060 $\mu g/m^3$** quartz dust.

D. Conditions which may affect exposure estimates

In the development of this screening assessment of exposure to respirable dust containing crystalline silica, a heavy reliance was made upon statistics provided by SMI concerning the "normal" use of pet litter. During the course of the evaluation, it became clear that certain conditions or factors which, although they may fall outside of "normal" use parameters, may occur with some frequency. We have tried to identify some of these factors, 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. SMI estimated that dust levels generated in an "open room" were approximately 40% of those generated in their experimental chamber. This factor was not incorporated into exposure estimates since average consumer room size where the litter box is located was not provided (large room vs. bathroom, closet, etc.)
- Exposure times less than those used in this assessment (<180 seconds for conventional litter; <140 seconds for scoopable litters)
- Fractional (<100%) absorption/retention of respirable particles from inhalation route
- Intermittent use of litter by pet (*e.g.*, outdoor option).

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

- Scooping of conventional litter. Some users of conventional pet litter may "scoop" solid animal wastes. The studies with scoopable litter indicate that daily scooping/clump removal activity on average generates similar levels of respirable quartz as daily pouring activity. If conventional litter also follows this pattern and is scooped daily, exposure estimates for scooping activity may increase exposure several fold. In the case of conventional litter, clump formation does not occur, so it would be expected that less "sifting" activity would need to be done relative to that with scoopable pet litter. Removal of solid animal wastes would result in the removal of only small amounts of litter, so no replenishment activity would need to be performed.
- Multiple pet households
- Presence of people in vicinity of litter box outside of filling/changing/replenishing activity
- Recirculation of litter dust from cleaning (or other) activity in the household
- Closer proximity to litter box than the estimates used in the exposure studies (short stature/arm length)
- Pet conditions which would increase litter use

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 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 focussed 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 pet litter. Thus, we expect that the screening potency estimates

presented above represent “worst case” estimates of the true potency for crystalline silica present in clay-based pet litter.

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 pet litter use, it is not anticipated that the breathing rate of the average user, during the course of pet litter-related activity, would be significantly greater than that of the workers from which the cancer slopes were derived.

IV. Discussion of Crystalline Silica (Quartz) Exposure Levels from Use of Clay-Based Pet Litters Relative to Cancer Potency Estimates

Estimates developed from the exposure data provided by SMI indicate that yearly average exposure levels to crystalline silica from the use of conventional pet litter products range from 0.0007 to 0.01 $\mu g/m^3$ quartz dust, while the use of scoopable pet litter products range from 0.0018 to 0.060 $\mu g/m^3$ quartz dust. With the assumption that a consumer uses a single product throughout his/her lifetime, the highest estimate produced is an annual time weighted average exposure of 0.06 $\mu g/m^3$ quartz dust for a scoopable pet litter product. This exposure level is approximately nine-fold lower than the lowest concentration (0.54 $\mu g/m^3$) associated with a risk of one in 100,000 persons exposed derived from occupational epidemiological studies. Because in this screening assessment these concentrations were below 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 of the average user of either conventional or scoopable pet litter under the conditions described in this assessment to respirable 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. 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.