

July 27, 2008

George Alexeeff, Ph.D.  
Deputy Director for Scientific Affairs  
Office of Environmental Health Hazard Assessment  
1001 I Street  
Sacramento, CA 95814

Dear Dr. Alexeeff:

This letter is being provided to inform the discussion regarding the utility of adding the cyclic siloxanes to the list of priority chemicals for biomonitoring in the California Environmental Contaminant Biomonitoring Program (CECBP). The Silicones Environmental, Health, and Safety Council of North American (SEHSC) is supportive of the use of biomonitoring as a tool for evaluating the potential risks associated with chemicals for which there are well-established human health hazards. We also recognize the potential value of biomonitoring for measuring the effectiveness of policies intended to reduce the presence of materials that have health risks for humans. However, given the lack of demonstrated human health risks for the cyclic siloxanes and the considerable expense associated with overcoming the technical challenges with monitoring these materials, it would not be useful to list the cyclic siloxanes as priority materials for the CECBP.

**Priority substances for biomonitoring should focus on materials that have demonstrated human health risks.**

As improvements in the precision and accuracy of modern laboratory analytical techniques have fundamentally changed the possibilities for identifying small quantities of substances in complex matrices, there has been a growing interest in using the technology to quantify the presence of chemicals in human tissue. Although advances in analytical techniques allow the assessment of many compounds, well designed biomonitoring programs should be structured to result in measurable public health benefits. As biomonitoring is a tool for evaluating potential human exposure, the inclusion of specific substances as priorities for a biomonitoring program should consider the significance of the risk posed by the material. Using biomonitoring data to assess the presence of a substance that has no human health risks does not provide substantive public health benefits. Substances that pose incrementally higher human

health risks should be assigned equivalently higher priority for biomonitoring. Conversely, substances that do not have measurable human health risks, such as the cyclic siloxanes, should be considered low priorities for biomonitoring.

**Comprehensive human health evaluations have been conducted by two regulatory authorities (Canada and the UK), and an independent product review expert panel for cyclic siloxanes. All of those assessments have noted that the materials do not pose a risk for human health.**

The human health risks for cyclic siloxanes have been evaluated extensively by regulatory agencies in Canada and the United Kingdom (UK). Both of those evaluations concluded that the cyclic siloxanes do not pose a risk for human health. In addition, the Cosmetic Ingredient Review (CIR) board, an independent panel of experts, has recently completed a separate assessment that also confirmed the safety of cyclic siloxanes for use in cosmetics.

While there is human exposure to cyclic siloxanes as a consequence of their use in consumer products, the physical-chemical properties of the materials, including their high volatility and low water solubility, minimize their bioavailability in human blood and plasma. Indeed, extensive animal and human pharmacokinetic data from dermal and inhalation exposure evaluations of D4 and D5 indicate rapid elimination in exhaled breath and extensive metabolism. Extensive safety testing has been completed on these materials and although some studies have identified effects in laboratory animals, these effects are seen at levels much higher than concentrations to which humans are exposed.

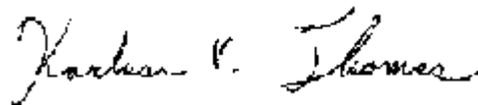
**Lack of human health risk coupled with the technical challenges associated with biomonitoring cyclic siloxanes indicates that these materials should be low priorities for the CECBP.**

There are a number of technical challenges associated with biomonitoring cyclic siloxanes. Because many products and equipment commonly found in scientific laboratories contain silicone-based materials, the potential for background contamination and analytical artifacts must be controlled. In addition, the inherent difficulties associated with biological monitoring for these materials in blood and plasma will require extensive method validation, a comprehensive QC program during sample collection, transport, storage, and analysis, and carefully controlled laboratories to ensure accuracy, precision, sensitivity, and specificity.

The complex analytical challenges inherent in measuring these materials accurately will significantly increase the cost and decrease the potential reliability of the results. Also, field crews must be careful not to introduce contamination during sample collection from

such sources as lubricants commonly used on field equipment, storage containers, or even personal care products such as hand creams or sunscreens. All of these factors could generate results that overestimate actual concentrations, especially when attempting to measure trace level concentrations at or near the limits of the analytical method. These factors coupled with the fact that these materials do not pose a risk for human health confirms the cyclic siloxanes should not be considered priority substances for the CECBP.

Sincerely,

A handwritten signature in cursive script that reads "Karluss Thomas".

Karluss Thomas  
Executive Director,  
SEHSC

Cc: Howard Berman  
OEHHA Science Guidance Panel