

## Research on the Safety of D<sub>4</sub>

### About D<sub>4</sub>

Octamethylcyclotetrasiloxane (D<sub>4</sub>) is an odorless, colorless non-oily silicone fluid used primarily to make other silicone materials. During this manufacturing process, virtually all of the material is consumed, with only a tiny amount of D<sub>4</sub> remaining. In a small handful of personal care products, D<sub>4</sub> can be used as an additive providing certain application-related benefits preferred by consumers.

### Key Research Findings and Relevance

D<sub>4</sub> is among the most extensively studied materials used in consumer and industrial applications. More than 30 studies have been conducted to evaluate D<sub>4</sub> from an environmental, health and safety perspective. Research to date affirms that when used as intended, D<sub>4</sub> is safe for consumers and workers.

The silicone industry continuously evaluates the safety of its materials. Of the many studies conducted with D<sub>4</sub>, there were a few findings that required further investigation to clarify the relevance to human health. Below are the specific findings and the follow-up investigations that provide the context to understand the overall significance of the data.

A series of tests exposing laboratory rats to high doses of D<sub>4</sub> by inhalation showed a reduction in the number of rat pups per litter and a disruption of the reproductive cycle. No change in other indicators of pup health and development were observed. Known human exposures to D<sub>4</sub> do not reach the concentrations at which these effects were observed. Even the lowest level that produced this effect in rats is thousands of times greater than the consumer exposure levels.

After repeated exposure to high concentrations of D<sub>4</sub>, some rats had an increase in liver weight. This response, which does not affect the animal's health, is well-documented and widely recognized. It is related to an increase of liver enzymes that metabolize and eliminate a material from the body. The increased liver weight reverses even while the D<sub>4</sub> exposure continues. The finding is not adverse, but is considered a natural adaptive change in rats.

In a two-year, combined chronic/carcinogenicity study, rats were exposed to D<sub>4</sub> by inhalation at levels up to the highest possible vapor concentrations. There were no findings in male rats. Data showed a statistically significant increase in a benign uterine tumor in female rats exposed at the highest level—a level much higher than the low levels that consumers or workers may encounter. Based on the finding in female rats, silicone manufacturers conducted extensive follow-up research to determine the cause of the finding. An expert panel of independent scientists who have reviewed the results of this research concur that the finding seen in the two-year study occurred through a biological pathway that is specific to the rat and is not relevant to humans. Therefore, this observed effect does not indicate a potential health hazard to humans.

### **Silicone Manufacturers' Commitment**

D<sub>4</sub> manufacturers are committed to worker and consumer safety. One concrete expression of this commitment is the \$30 million voluntary Siloxane Research Program that aims to enhance current knowledge about the safety of siloxanes in consumer and industrial applications. As a part of this program, study methods and results are reviewed by a panel of independent scientific experts, and study results are published in peer-reviewed scientific publications. This initiative represents the largest voluntary health and safety program ever conducted on siloxanes.

Silicone manufacturers continue to communicate the results of this research initiative to regulatory agencies, employees, and customers. Based on the extensive data available for D<sub>4</sub>, silicone manufacturers continue to support the safe use of D<sub>4</sub> when used as intended. ■

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SEHSC is a not-for-profit trade association comprised of North American silicone chemical producers and importers. For more than 30 years, SEHSC has promoted the safe use of silicones through product stewardship and environmental, health, and safety research. The organization also is involved in legislative and regulatory issues relating to silicone materials.