

## Siloxane $D_5$ in Drycleaning Applications



EPA has received results of a cancer study on Siloxane  $D_5$  in rodents, submitted under TSCA section 8(e). The results of this study indicate that there may be a cancer hazard associated with  $D_5$ . However, the Agency has not conducted a risk assessment for  $D_5$ , and, therefore, is not in a position to characterize potential risks to human health, or the environment associated with  $D_5$  use in drycleaning.

What is "Siloxane D<sub>5</sub>"?

Decamethylcyclopentasiloxane, or  $D_5$ , is an odorless, colorless liquid that has many consumer and industrial applications.  $D_5$  is used as an ingredient in a number of personal health and beauty products, including deodorants, antiperspirants, cosmetics, shampoos, and body lotions. It is also used as a drycleaning solvent and in industrial cleaning.

Have Other Studies Been Conducted?

The subject cancer study is one of a broad range of toxicological studies on  $D_5$  and several other siloxanes that are being conducted voluntarily by the Dow Corning Corporation under a Memorandum of Understanding signed with EPA in 1996.

What are the results of the study?

In February 2003, EPA received from Dow Corning the preliminary results of a two-year chronic toxicity and carcinogenicity study on  $D_5$  using rats. In this study, groups of 60 male and 60 female Fischer 344 rats were exposed to vapor concentrations of 0, 10, 40, or 160 ppm of  $D_5$  for 6 hours per day, 5 days per week, for 24 months. The preliminary results show that female rats exposed to the highest concentration of  $D_5$  exhibited a statistically significant increase of uterine tumors.

In July, 2005 EPA received the final results of the two-year study in rats, which confirmed the significant increase in uterine tumors following exposure to 160 ppm of D5, the highest concentration tested in the study. No significant increase in tumors was observed at lower doses.

How were the results submitted?

Dow Corning submitted the results of their study under section 8(e) of the Toxic Substances Control Act (TSCA). Section 8(e) requires that U.S. chemical manufacturers notify EPA of information that could support a conclusion of substantial risk of injury to health or the environment. Section 8(e) submissions most often contain toxicity data, but may also contain information on exposure, environmental persistence, or actions being taken to reduce human health and environmental risks.

How will EPA follow up?

In addition to the two-year study, EPA received a series of studies that Dow Corning conducted to determine the specific mode of action for the D5-induced uterine tumors in rats. This information may help determine whether a potential carcinogenic hazard is associated with  $D_5$  for humans. EPA is in the process of evaluating these studies, and anticipates that the mode of action analysis will be complete by the end of 2006. If EPA determines that a mode of action has been established, the analysis will subsequently be submitted for an external peer review. While EPA completes the analysis of the mode of action, EPA remains interested in receiving data on human exposure to  $D_5$ , including drycleaning applications. After evaluating the mode of action analysis, EPA, in consultation with other relevant Federal agencies, will determine whether it is appropriate to conduct a risk assessment for  $D_5$ .

Office of Pollution Prevention and Toxics (7404) 744-F-03-004 December 2005