



Siloxane D₅ in Drycleaning Applications Fact Sheet



EPA has received the preliminary results of a cancer study on Siloxane D_5 in rodents, submitted under TSCA section 8(e). The preliminary results of this study indicate that there may be a cancer hazard associated with D_5 . However, the Agency has not conducted a screening-level or formal 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**₅"?

Have Other Studies Been Conducted?

What are the preliminary results?

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.

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.

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. These preliminary findings may indicate that there is a potential carcinogenic hazard associated with D_5 .

How were the results submitted?

How will EPA follow up? Because of rodent uterine tumors that were noted in the study, 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.

Given the uncertainties, EPA cannot make a determination on potential risk to human health from D_5 until final results from the study are available, appropriate exposure information is developed, and a quantitative risk assessment is conducted. EPA expects that Dow Corning will deliver the final results of their two-year chronic toxicity and carcinogenicity study on D_5 in the Spring of 2004. While the study is being finalized, EPA remains interested in receiving data on human exposure to D_5 including drycleaning applications. Upon receipt of the final report of the bioassay, EPA, in consultation with other relevant Federal agencies, will determine whether it is appropriate to conduct a risk assessment for D_5 .

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