

# SilSense<sup>®</sup> IWS Silicone Toxicology Studies

**CTFA / INCI Name: Dimethiconol Stearate**

## Acute Oral Toxicity

The acute oral toxicity of SilSense<sup>®</sup> IWS silicone was studied in rats according to FHSLA, 16 CF 1500.3. Five male and five female rats were administered a single dose of 5,000 mg/kg via gavage. The animals were housed individually and observed for mortality and clinical signs of toxicity for 14 days following exposure. No evidence of toxicity was observed. The acute oral LD<sub>50</sub> was determined to be greater than 5,000 mg/kg.

## Eye Irritation

The potential for SilSense IWS silicone to cause eye irritation was evaluated according to FHSLA, 16 CFR 1500.42. A dose of 0.1 ml of the test material was administered to eyes of six rabbits. The eyes were evaluated according to the method of Draize et al.<sup>1</sup> The Draize scores were then classified according to the method of Kay and Calandra.<sup>2</sup> The eyes were evaluated at 24, 48, and 72 hours following exposure. The Maximum Mean Total Score was determined to be 0.00. Based on these results the test material was considered to be non-irritating.

## Skin Irritation

The skin irritation potential of SilSense IWS silicone was evaluated according to FHSLA, 16 CFR 1500.41. A dose of 0.5 g of the test material was applied to the intact and abraded skin of six rabbits and then covered by occlusive patches. The skin was evaluated at 24 and 72 hours. The Primary Irritation Index was determined to be 0.00. Based on these results the test material was not considered to be a primary skin irritant.

<sup>1</sup> Draize et al., (1944) J. Pharmacol. Exp. Ther. 83:377-390.

<sup>2</sup> Kay and Calandra, (1962) J. Soc. Cos. Chem. 13:281-289.

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