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13-Week Oral Gavage Toxicity with Sophora Japonica Linne Seed Extract in Sd Rats

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In this GLP study, 4 study groups of 12 Sprague-Dawley (SD) rats/sex were given vehicle, or 1,000, 1,500, or 2,000 mg/kg/day Sophora Japonica Linne Seed Extract (SE) for 13 weeks.

Standard endpoints in this study included mortality, clinical observations, body weight, food and water consumption, ophthalmoscopic examination, urinalysis, hematology, serum biochemistry, organ weights, gross anatomic pathology and histopathology.

There were no treatment-related clinical signs, change of body weights, and change of food and water consumption. There were also no treatment-related findings in opthalmoscopic examination, urinalysis, hematology and serum biochemistry.

Relative weights of livers and kidneys were significantly increased in male given 1,500 and 2,000 mg/kg. Absolute and relative weights of livers were significantly increased in female given 1,500 and 2,000 mg/kg. However, there were no findings by histopathological examination of tissues.

Spontaneous disease lesions were noted in lung, kidney, mammary gland and uterus and were equally prevalent among control and treated animals and thus not attributed to administration of SE.

It was concluded that doses of 2000mg/kg were no-observed-effect levels (NOEL) when given by oral gavage to male and female SD rats for 13 week.

Keyword : Sophora Japonica Linne Seed Extract (SE), repeated toxicity