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Toxicity studies on ethyl acetate soluble proanthocyanidins and aqueous extract of the immature inflorescence of *Cocos nucifera* L. in female Wistar rats.

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Ayurvedic and traditional medical practitioners of Sri Lanka use the aqueous extract (AE) of the immature inflorescence of *Cocos nucifera* L. (IC) var. *aurantiaca* for the treatment of menorrhagia. The progestogenic effect of the ethyl acetate soluble proanthocyanidins (EASPA) of the IC in female rats at a dose of 3.5 mg/kg body weight has been reported. Acute and subacute toxicity studies of both EASPA and EA of the IC carried out using female Wistar rats according to the Organization for Economic Co-operation and Development (OECD) guidelines 423 and 407, respectively, are reported herein. In the acute toxicity study, a single dose of EASPA (2000 mg/kg body weight) was orally administered to the rats, which were monitored for 14 days. In the subacute toxicity study, rats were orally administered with EASPA daily, for 28 days, at doses of 1.75, 3.5, 7, and 14 mg/kg body weight. Acute and subacute toxicity studies of AE were carried out in a similar manner to those of EASPA. Dose levels of 150, 300, 600 and 1200 mg/kg body weight of AE were used for the subacute toxicity study. No rat in either of the acute or subacute toxicity studies of EASPA exhibited mortality or clinical signs of toxicity. Further, these treated rats did not show any significant changes in their mean body weight, food, and water intake, haematological and biochemical parameters as well as in the results of their histopathological examinations compared to those of control group rats. Similar observations were made for treated rats in both acute and subacute toxicity studies of EA. However, in the acute toxicity study of EA, histopathological examination of liver of treated rats showed some signs of toxicity indicating hepatotoxic nature of EA at the tested dose level. According to results of the acute toxicity, the LD50 of EASPA and AE are estimated to be greater than 2000 mg/kg body weight. Considering the results of the subacute toxicity study, the oral administration of EASPA and EA daily for 28 days was well tolerated, up to the doses 14 and 1200 mg/kg respectively, by rats. These results will be useful in the development of a novel therapeutic agent from EASPA of the IC for the treatment of menorrhagia, which incapacitates a considerable proportion of women worldwide.

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