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A 13-week subchronic toxicity study of garden balsam extract in F344 rats

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Abstract

A subchronic toxicity study of garden balsam (*Impatiens balsamina* L.) extract (GBE) was performed in male and female F344 rats with oral administration in their drinking water at concentrations of 0%, 1.25%, 2.5%, and 5.0% for 13 weeks. No chemical-related clinical signs and changes of body weights, food intake, and water consumption were observed in any groups during the experiment. Regarding serum biochemistry, in males, significant increase of Na was observed in 2.5% and 5.0% group and that of Cl was seen in all treated groups. In females, significant increase of Cl and decrease of inorganic phosphorus (IP) were detected at 2.5% and 5.0%. However, no related histopathological lesions were observed in the kidney, intestine and bone tissue. Therefore, it is considered that the changes in serum electrolyte levels were not associated with any meaningful toxicological effects. There were no significant differences in hematological data, organ weights and histopathological findings among the groups. Based on the results, the no-observed-adverse-effect level (NOAEL) for GBE in male and female F344 rats was estimated to be more than 5.0% (3997 and 4577 mg/kg bw/day, respectively).

Keywords : garden balsam extract, F344 rats, *Impatiens balsamina*, subchronic toxicity

I Introduction

Garden balsam extract (GBE) is derived from the garden balsam (*Impatiens balsamina* L., Balsaminaceae), annual ornamental herb which originated in South to Southeast Asia, by ethanol extraction of whole plant bodies. GBE has been traditionally used as a folk medicine in the Asian countries[1] and also categorized as a food additive for its anti-oxidative effects[2]. A wide variety of chemicals have been reported as active components of GBE, including phenolic acids[3], naphthoquinone derivatives[4, 5], coumarin derivatives[6], flavonoid glycosides[7, 8], triterpene glycosides[9-11], and sterols[12]. A number of studies have demonstrated that GBE exhibits various preventive and inhibitory effects against pruritus[5], anaphylaxis[13, 14], microbial growth[1, 15, 16], cyclooxygenase-2 activity[17], and Wnt signaling[18].

Regarding safety assessment, GBE has been shown to be negative in several mutagenicity assays such as the Ames test, Chinese hamster's chromosomal aberration test and mouse bone marrow micronucleus assay[19]. However, there have been no reports from longer-term *in vivo* animal experiments investigating the toxicological effects of GBE neither in rats nor mice. We have provided new knowledge concerning toxicological observation of a number of food additives such as madder color, tocotrienol, kojic acid, and horseradish extract in animal models[20-23]. In the present study, we therefore performed a 13-week subchronic toxicity study with oral administration of GBE to F344 rats to establish the no-observed-adverse-effect level (NOAEL).

II Materials and Methods

1. Test chemical

The GBE provided from the division of standards and evaluation, department of food safety, Ministry of Health,

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