

## 28-Day Oral Toxicity of Macrophomopsis Gum in F344/DuCrj Rats

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### Abstract

The potential toxicity of *Macrophomopsis* gum was investigated in groups of 6 F344 rats of each sex given powdered diet containing the compound at 0, 1.25, 2.5 or 5.0% for 28 days.

Significant treatment-related effects of *Macrophomopsis* gum treatment included the following: lowered food efficiency in males and females of the 5.0% group. In leukocyte differentiation counts, lowered segment neutrophil values were observed in all male treated groups. Elongated prothrombin time was noted in the 2.5 and 5.0% male groups and elevated total bilirubin in the 2.5 and 5.0% female groups. Lowered total cholesterol values were noted in the 5.0% males and 2.5% females. Lowered phospholipid was noted in the 5.0% male group and lowered total protein in the 2.5 and 5.0% male groups. Lowered albumin was noted in the 2.5% male group. None of these minor variations observed in the food efficiency, hematology and blood biochemistry are considered to be indicative of any treatment-related toxic effect.

In addition, no toxicologically significant treatment-related effects were noted regarding clinical signs, survival rate, body weights, food consumption, water intake, urinalyses, ophthalmology, gross pathology, organ weights and histopathology findings.

The present results indicate that the no observed adverse effect level for 28 days dietary treatment is 5.0% (males: 3,956 mg/kg/day, females: 4,257 mg/kg/day).

**Key words:** Subacute toxicity, *Macrophomopsis* gum, F344 rats

### 1. Introduction

*Macrophomopsis* gum has been developed to augment the viscosity of processed food as a thickener, stabilizer, emulsifier and paste agent and is approved as an existing food additive for a viscosity stability by the Japanese Ministry of Health, Labour and Welfare. A major component is a high-molecular-weight polysaccharides including beta-1,3-glucan and dextran obtained by *macrophomopsis* cultivation<sup>1)</sup>. Many similar fermented polysaccharides such as xanthan gum and gum karaya, and naturally occurring polysaccharides such as agar, guar gum, gum Arabic, locust-bean gum, tara gum and tragacanth gum, have been developed for the same purpose. Toxicological investigations of

these polysaccharides have been documented including carcinogenicity studies, and no adverse toxicological or carcinogenic effects have hitherto been evident<sup>2-9)</sup>. An increased amount of cecal contents and/or cecal enlargement are well known effects of several gums, including xanthan gum, guar gum or gum Arabic, and ethyl acetoacetate<sup>5, 10-12)</sup>. These effects are considered to be physiological adaptation<sup>13, 14)</sup>. 0.2~0.5% *Macrophomopsis* gum had been used in jellies and thus human ingestion is estimated to be very low. However, no toxicological investigations of *Macrophomopsis* gum have been reported. The present investigation was therefore undertaken to evaluate the subacute toxicological potential of *Macrophomopsis* gum given 28 days in the diet to both sexes of F344 rats.