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ACCEPTED MANUSCRIPT

Acute and subchronic oral toxicity studies of hydrogenated curcuminoid formulation 'CuroWhite' in rats

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Abstract

Hydrogenated curcuminoids are the major metabolites of the curcumin and 'CuroWhite' is a unique blend of hydrogenated curcuminoids encapsulated with β-cyclodextrin. There is no particular scientific evidence for the toxicology regarding the hydrogenated curcuminoids, so the present work reports the results of the studies investigating the acute (single dose) and subchronic (repeatedly 90 days) oral toxicity of the CuroWhite in Sprague Dawley rats. For acute oral toxicity testing a sighting study was conducted on female rats in a sequential manner to allow selection of the appropriate starting dose for the main study. In acute toxicity, the dosage was 2000mg/Kg body weight for four female rats. In the sub-chronic study, rats of both sexes divided into three groups and each group were orally treated with CuroWhite daily at 200, 400 and 800 mg/Kg for 90 days consecutively. No evidence of treatment related toxicity was detected during the study. Thus, data analysis of mortality, body weight gain, feed consumption, clinical observations, haematology, organ weights and histopathological findings did not show significant differences between control and treated groups. It is concluded that CuroWhite orally administered to rats was safe and no drugrelated toxicity was detected even at the highest doses investigated in both acute (2000 mg/Kg) and subchronic toxicity (200, 400 and 800 mg/Kg) studies. Based on the study, the no-observed-adverse-effect level (NOAEL) value could be considered as 800 mg/kg per day in both the sexes. These results indicate that CuroWhite can be generally regarded as safe for use as a food additive.

Keywords: CuroWhite, Acute oral toxicity, Subchronic oral toxicity, Sprague Dawley rats

1. Introduction

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