

# Toxicological Analysis of a Standardized Hydrogenated Extract of Curcumin: Assessing Safety and Potential Health Risks

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## Abstract

Ingesting curcumin by itself does not lead to the associated health benefits due to its poor bioavailability, which appears to be primarily due to poor absorption, rapid metabolism, and rapid elimination. There are several components that can increase bioavailability. It may also help in the management of exercise-induced inflammation and muscle soreness, thus enhancing recovery and performance in active people. However, the poor bioavailability and stability of curcumin have been major limitations. In response to this challenge, researchers have explored different methods to enhance its pharmacological properties, including the hydrogenation of curcumin. In this article, we present a toxicological evaluation of a standardized hydrogenated extract of curcumin to assess its safety for potential therapeutic applications. Two mortalities occurred in the main and satellite high-dose groups and were determined due to gavage error.

**Keywords:** Hexahydrocurcumin; Turmeric; Antioxidant; Anti-inflammatory; Polyphenol

## Introduction

Curcumin and its structural analogues have many biological activities, such as cytoprotection, antioxidant activity, inflammatory response modification, cardiovascular support, neuroprotection, and radioprotection. Catalytic hydrogenation of curcumin leads to tetrahydrocurcumin, hexahydrocurcumin, and octahydrocurcumin. These are the major metabolites of curcumin; like their parent compounds, they have many biological activities [1]. Hydrogenated curcuminoids have higher bioavailability while encapsulated with  $\beta$ -cyclodextrin compared with curcumin. B-Cyclodextrin acts as a lipophilic cage and hence increases the aqueous solubility and stability of the active molecules.

CuroWhite is a unique formulation of hydrogenated curcuminoids encapsulated with -cyclodextrin. However, there are no studies available investigating the potential toxic effects of hydrogenated curcuminoids. Our research group conducted acute and subchronic oral toxicity studies of CuroWhite in rats and briefly summarized the results previously. In the present work, we report the genotoxicity studies and provide detailed reporting of the previously summarized subchronic study of the hydrogenated curcuminoid formulation, CuroWhite. It has been shown to benefit inflammatory conditions, metabolic syndrome, pain, and to help in the management of inflammatory and degenerative eye conditions. In addition, it has been shown to benefit the kidneys. While there appear to be countless therapeutic benefits to curcumin supplementation, most of these benefits are due to its antioxidant and anti-inflammatory effects [2]. Despite its reported benefits via inflammatory and antioxidant mechanisms, one of the major problems with ingesting curcumin by itself is its poor bioavailability, which appears to be primarily due to poor absorption, rapid metabolism, and rapid elimination. Several agents have been tested to improve curcumin's bioavailability by addressing these various mechanisms. Most of them have been developed to block the metabolic pathway of curcumin in order to increase its bioavailability.

## Acute toxicity assessment

Acute toxicity studies were conducted to determine the lethal dose of the hydrogenated curcumin extract in animal models. Various doses were administered, and the animals were observed for signs of toxicity

and mortality [3]. The results indicated that the extract exhibited low acute toxicity, with no observed mortalities or significant adverse effects at the tested doses [4].

## Subchronic and chronic toxicity studies

Subchronic and chronic toxicity studies were conducted to assess the potential toxic effects of prolonged exposure to the hydrogenated curcumin extract [5]. Animals were exposed to the extract for an extended period, and a comprehensive evaluation of various organs, biochemical parameters, and histopathological changes was performed. These studies revealed no significant toxicity or adverse effects, suggesting that the hydrogenated curcumin extract is well-tolerated even with long-term exposure [6].

## Genotoxicity and mutagenicity assessment

Genotoxicity and mutagenicity evaluations were carried out to assess the potential DNA-damaging and mutagenic effects of the hydrogenated curcumin extract [7]. A battery of standardized tests, including the Ames test and micronucleus assay, were conducted using bacterial and mammalian cell models. The results consistently demonstrated no genotoxic or mutagenic potential, suggesting the extract's safety in terms of DNA integrity [8].

## Carcinogenicity studies

Carcinogenicity studies were conducted to investigate the potential for the hydrogenated curcumin extract to induce tumor formation or promote cancer development [9]. Animals were exposed to the extract for an extended duration, and their overall tumor incidence, growth,

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and metastasis were assessed. The findings revealed no evidence of carcinogenicity, indicating that the hydrogenated curcumin extract does not pose an increased risk of cancer development [10].

## Conclusion

While this toxicological evaluation indicates the safety of the standardized hydrogenated extract of curcumin, it is important to note that further studies, including clinical trials, are necessary to fully understand its efficacy and safety in humans. As with any new therapeutic intervention, careful evaluation and monitoring are essential to ensure the optimal use of curcumin and its derivatives for human health and well-being. Curcumin has received worldwide attention for its multiple health benefits, which appear to act primarily through its anti-oxidant and anti-inflammatory mechanisms. These benefits are best achieved when curcumin is combined with agents such as piperine, which increase its bioavailability significantly. Research suggests that curcumin can help in the management of oxidative and inflammatory conditions, metabolic syndrome, arthritis, anxiety, and hyperlipidemia. It may also help in the management of exercise-induced inflammation and muscle soreness, thus enhancing recovery and subsequent performance in active people. In addition, a relatively low dose can provide health benefits for people that do not have diagnosed health conditions. Ionally, genotoxicity and mutagenicity assessments suggest that the extract does not induce DNA damage or mutations. Furthermore, carcinogenicity studies demonstrate no evidence of increased cancer risk associated with the hydrogenated curcumin extract.

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