AN ACUTE ORAL TOXICITY STUDY IN RATS WITH SIMMONDSIN (JOJOBA EXTRACT)

DRAFT REPORT

Guideline

FDA-CPSC

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Study Completed on

Performing Laboratory

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SLI Study No.

3624.1

Submitted to

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INTRODUCTION

This study was performed to assess the short-term toxicity of Simmondsin (Jojoba Extract) in Sprague Dawley rats when administered by gavage as a single oral dose. This study was intended to provide information on the potential health hazards of the test article with respect to oral exposure. Data from this study may serve as a basis for classification and/or labeling of the test article. This study was performed at Springborn Laboratories, Inc., 553 North Broadway, Spencerville, Ohio. The protocol was signed by the Study Director on October 8, 2002 (GLP initiation date). The in-life phase of the study was initiated with test article administration on October 9, 2002 (day 0) and concluded with necropsy on October 23, 2002.

SUMMARY

The single-dose oral toxicity of Simmondsin (Jojoba Extract) was evaluated in Sprague Dawley rats. A limit test was performed in which one group of five male and five female rats received a single oral administration of the test article at a dose of 5000 mg/kg body weight. In addition, five male and five female rats received deionized water at the same dose volume as the test group in order to serve as a control group. The study design is as follows:

Group	Test Material	Dose Level (mg/kg)	Concentration (mg/mL)	Dose Volume (mL/kg)	No. of Animals	
					Male	Female
1- Control	Deionized water	0	0	10	5	5
2- Test	Simmondsin (Jojoba Extract)	5000	500	10	5	5

Following dosing, the study rats were observed daily and weighed weekly. A gross necropsy examination was performed on all animals at the time of scheduled euthanasia (day 14). All tissues for each animal were examined histopathologically.

No mortality occurred during the study. Clinical abnormalities observed during the study included unkempt appearance, fecal staining, ocular discharge, and dark material around the facial area. Body weight gain was noted for all animals during the test period. No significant gross internal findings were observed at necropsy on study day 14. The histopathology examination concluded that there were no microscopic lesions caused by the test article.

Under the conditions of this test, the acute oral LD50 of Simmondsin (Jojoba Extract) was estimated to be greater than 5000 mg/kg in the rat.

(CONCLUSION: There was no toxicity observed with Simmondsin/Jojoba Extract. In addition all animals survived, therefore the oral toxicity must be greated than the maximum administered dose of 5000 mg/kg.)