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FINAL REPORT

Test Facility Study Code: 31989617

A 90-Day Repeated Dose Toxicity Study of AC-Oxyrase by Oral (Gavage) in Wistar Rats

GLP

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1. SUMMARY

The objective of this study was to obtain information on the possible toxic effects of the test item when administered daily for consecutive 90 days by oral gavage to Wistar rats. This repeated dose toxicity study in the rat was performed in accordance with the OECD test guideline No. 408. to meet the regulatory requirements for a novel food project with a maximal dose level of 200-750 mg/kg bw/day of the supplied liquid products.

Forty male and 40 female Wistar rats were treated once daily for consecutive 90 days by oral gavage administration according to the following experimental design.

Gr. No.	Group Designation	Dose Levels (mg/kg bw/day)	Dose Concentration (mg/mL)	Dose volume (mL/kg)	Animal Identification	
					male	female
1	Control	0	0	1	1001-1010	1501-1510
2	Spent fermentation media	0	0		2001-2010	2501-2510
3	Fragmented cell group	200	200		3001-3010	3501-3510
4	Whole cell group	750	500	1.5	4001-4010	4501-4510

Control animals received the vehicle (distilled water). Body weight, food consumption and clinical signs were recorded during the in-life phase. Ophthalmoscopy was performed before start and on the last week of the treatment. Functional Observation Battery (FOB) and measurement of locomotor activity were performed in Week 13. Blood samples were collected prior to necropsy for clinical pathology and thyroid hormone analysis. Oestrous cycle, sperm analysis, organ weight, macroscopic and histopathology investigations were undertaken.

Results

No mortality occurred during the study.

No test item related clinical observations were recorded, and no test item related changes were observed in body weight, body weight gain or food consumption throughout the study in the dosed groups.

There was no effect of test item noted during the assessment of grip strength, foot splay, Irwin Test or locomotor activity (LMA) in any dose group when compared to control animals.

No abnormalities were recorded during ophthalmic evaluation at pre-test or at the end of the treatment period.

No test item related changes were observed in the measured haematology, coagulation or clinical chemistry parameters. No test item related effect was seen in the measured T3, T4 and TSH thyroid hormone parameters.

There were no test item-related observations in the animal oestrus cycles. There was no effect on testicular pathology.

During pathology investigation, there were no organ weight findings and no macroscopic or microscopic histological changes in organs or tissues related to the test item.