

ACUTE ORAL TOXICITY IN RATS – LIMIT TEST

TEST METHOD NO.: P203

STUDY NUMBER: 12797

SPONSOR NuScience Corporation
43102 Business Center Pkwy
Lancaster, CA 93535

TEST SUBSTANCE IDENTIFICATION: Cellfood

TEST SUBSTANCE DESCRIPTION: Light amber colored liquid

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NOTEBOOK NO.: 02-56: pages 287-291

1. PURPOSE

To provide information on health hazards likely to arise from short-term exposure to Cellfood by the oral route.

2. PROCEDURE

A group of Sprague-Dawley derived, albino rats was received from Ace Animals, Inc., Boyertown, PA. The animals were singly housed in suspended stainless steel caging with mesh floors. Litter paper was placed beneath the cages and was changed at least three times per week. The animal room was temperature controlled and had a 12-hour light/dark cycle. The animals were fed Purina Rodent Chow #5012 and filtered tap water was supplied *ad libitum* by an automated watering system.

Following acclimation to the laboratory, a group of animals was fasted overnight by removing feed from their cages. After the fasting period, ten rats (five male and five female) were selected for test based on health and initial bodyweights. Individual doses were calculated based on these bodyweights, taking into account the specific gravity of the test substance. Each animal received 5,000 mg/kg of the test substance by intubation using stainless steel ball-tipped gavage needle attached to an appropriate syringe. After administration, each animal was returned to its designated cage. Feed was replaced approximately 3 hours after dosing.

The animals were observed for mortality, signs of gross toxicity and behavioral changes at approximately on hour post dosing and at least once daily for 14 days. Bodyweights were recorded prior to initiation and at termination. All animals were euthanized by CO₂ inhalation at termination.

3. RESULTS

Individual bodyweights and doses are presented in Table 1. Cage-side observations are presented in Table 2.

All animals survived, gained weight and appeared active and healthy. There were no signs of gross toxicity, adverse pharmacological effects or abnormal behavior.

4. CONCLUSION

Under the conditions of this study, the single dose acute oral LD₅₀ of Cellfood is greater than 5,000 mg/kg of bodyweight in male and female rats.

TABLE1: INDIVIDUAL BODYWEIGHTS AND DOSES

Animal No.	Sex	Bodyweight (g)		Dose ¹
		Initial	Day 14	ml
5413	M	270	369	1.3
5414	M	261	388	1.3
5415	M	262	374	1.3
5416	M	273	380	1.3
5417	M	257	366	1.2
5418	F	200	247	0.97
5419	F	193	239	0.93
5420	F	184	236	0.89
5421	F	180	244	0.87
5422	F	174	232	0.84

TABLE: INDIVIDUAL CAGE-SIDE OBSERVATIONS

<u>Animal Number</u>	<u>Findings</u>	<u>Day of Occurrence</u>
<u>MALES</u>		
5413-5417	Active and healthy	0-14
<u>FEMALES</u>		
5418-5422	Active and healthy	0-14