Salmonella-Escherichia coli / Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay (ABSTRACT)

Test Article	G-63 Powder
Author	Michael S. Mechhi, MS
Sponsor	Graminex 95 Midland Road Saginaw, Michigan 48603
Test Facility	Covance Laboratories Inc. 9200 Leesburg Pike Vienna, Virginia 22182-1699
Covance Study Number	7740-102
Genetic Toxicology Assay Number	27995-0-409OECD
Report Issued	28 June 2006
Page Number	1 of 50

Abstract

The objective of this study is to evaluate the test article G-63 Powder, and/or its metabolites for their ability to induce reverse mutations at the histidine locus in several strains of *Salmonella typhimurium*, and at the typtophan locus of *Escherichia coli* strain WP2*uvr*A, in the presence or absence of an exogenous mammalian activation system (S9) containing microsomal enzymes.

The doses tested in the mutagenicity assay were selected based on the results of a dose rangefinding study using tester strains TA100 and WP2*uvr*A (pKM101) and ten doses of test article ranging from 6.67 to 5000 µg per plate, one plate per dose, both in the presence and absence of S9 mix (see Protocol Deviations).

The tester strains used in the mutagenicity assay were *Salmonella typhimurium* tester strains TA98, TA100, TA1535, and TA1537 and *Escherichia coli* tester strain WP2*uvr*A. The assay was conducted with six doses of test article in both the presence and absence of S9 mix along with concurrent vehicle and positive controls using three plates per dose. The doses tested were 33.3, 100, 333, 1000, 3330, and 5000 µg per plate in both the presence and absence of S9 mix. The results of the initial mutagenicity assay were confirmed in an independent experiment.

The results of the *Salmonella-Escherichia coli*/Mammalian-Microsome Reverse Mutation Assay with a Confirmatory Assay indicate that under the conditions of this study, the test article, G-63 Powder, did not cause a positive increase in the mean number of revertants per plate with any of the tester strains either in the presence of absence of microsomal enzymes prepared from Aroclor^{IM}-induced rat liver (S9).