**Bacterial Reverse Mutation Assay with PROJECT 8 (2441-009)**

**SUMMARY AND CONCLUSION**

The test article, PROJECT 8, was tested to evaluate its mutagenic potential by measuring its ability to induce reverse mutations at selected loci of several strains of Salmonella typhimurium and at the tryptophan locus of Escherichia coli strain WP2 uvrA in the presence and absence of an exogenous metabolic activation system. Dimethyl sulfoxide (DMSO) was used as the vehicle.

In the preliminary toxicity assay, the dose levels tested were 6.67, 10.0, 33.3, 66.7, 100, 333,

667, 1000, 3333 and 5000 μg per plate. Precipitate was observed beginning at 3333 μg per plate. Toxicity, as a reduction in revertant counts, was observed beginning at 1000, 3333 or at 5000 μg per plate with several test conditions. Based upon these results, the maximum dose tested in the mutagenicity assay was 5000 μg per plate.

In the mutagenicity assay, the dose levels tested were 15.0, 50.0, 150, 500, 1500 and 5000 μg per plate. Precipitate was observed beginning at 1500 μg per plate. Toxicity was observed beginning at 1500 or at 5000 μg per plate with most test conditions. No positive mutagenic responses were observed with any of the tester strains in either the presence or absence of S9 activation.

These results indicate PROJECT 8 was negative for the ability to induce reverse mutations at selected loci of several strains of Salmonella typhimurium and at the tryptophan locus of Escherichia coli strain WP2 uvrA in the presence and absence of an exogenous metabolic activation system.